

**Responses to Region 2's Comments Received June 5, 2015 on the
Draft Lower Passaic River Study Area Baseline Human Health Risk Assessment
Delivered June 2014 by the Lower Passaic River Study Area Cooperating Parties Group**

<u>No.</u>	<u>General Comment</u>	<u>CPG Response</u>
1	<p>Portions of the document highlight disagreements with EPA and, in some cases, reinterpretations of EPA's risk assessment Guidelines, Policies and Guidance that were previously addressed during the public and peer-review of EPA documents. EPA's review process is to release documents for public comment, go through external peer-review, respond to peer-review and public comments, and then finalize documents. It is inappropriate to reopen this process in a site-specific risk assessment such as that for the Lower Passaic River.</p> <p>Many issues, such as the fish ingestion rates, fraction ingested, and evaluation of cooking loss, were previously addressed in the dispute resolution. Other issues, such as the selection of toxicity values for PCBs and the non-cancer assessment for dioxin, were addressed in the development of the IRIS chemical file. The document needs to concentrate on presenting information in a manner that is understandable to both the manager and stakeholders and not on introducing alternative views of risk assessment. The restatement of disagreements addressed in the dispute resolution and also during public comments on EPA Guidelines, Guidance and Policies does not serve the purpose of the risk assessment and confuses the results of the analysis. The document will require extensive revisions to address this issue.</p> <p>Several instances of this concern are noted in the specific comments, but this issue should be addressed throughout the report.</p>	<p>The CPG disagrees with the Region's assertion that the document discusses issues that do not serve the purpose of the risk assessment or confuse the results of the analysis, or reinterprets EPA guidance and policy. In keeping with EPA's goal of transparency (USEPA 1992, 1995), the document discusses key issues and scientific debates on topics relevant to the public and risk managers' understanding of site risks.</p> <p>EPA's Risk Characterization guidance states that key scientific data and methods and their uncertainties should be identified, and information on the range of exposures and the use of multiple risk descriptors should be presented "to ensure a full and complete analysis of risk in the decision-making process" (USEPA 1992). The Region's comments in many instances serve to remove, minimize or obscure valid areas of uncertainty or disagreement. This approach does not achieve the Agency's objective of transparency in risk assessment documents, and serves to overstate site risk without providing appropriate and important context for the public and decision-makers.</p> <p>Consistent with guidance, the discussions of alternative assumptions and approaches and associated impact on risk are presented primarily in the uncertainty evaluation of the report. As stated in RAGS guidance <i>Section 8.4, Assessment and Presentation of Uncertainty</i>, "it is important to fully specify the assumptions and uncertainties inherent in the risk assessment to place the risk estimates in proper perspective" (USEPA 1989b). EPA's requests in several specific comments that discussions of alternative assumptions or approaches in the uncertainty section be removed are inconsistent with guidance and sound risk assessment practice. Further, during the 2012 EPA-CPG dispute resolution meeting for the RARC, Walter Mugdan made clear that discussions of alternate perspectives and issues where CPG's opinion differed from that of Region 2 could be</p>

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		<p>presented in the uncertainty evaluation.</p> <p>In summary, the CPG does not agree that extensive revisions to the text are needed to address this comment.</p>
2	<p>Risk summary tables in the Executive Summary should present numerical risk estimates and not simply identify whether the potential risk or hazard index (HI) was greater than or less than NCP guidelines (i.e., cancer risks of 10^{-4} and HI values of one). In addition, the risk summary tables in Section 6 should display this information more prominently (for example, the tables on Pages 6-6 through 6-24 should list numerical results). The degree to which NCP guidelines are exceeded is significant and should be presented and discussed in the main body of the report. The color-coding used to flag total risks and/or HIs that exceed guidelines is helpful and can be retained. Several areas of the report, particularly Sections 6.3 and 6.4, will need to be rewritten to address this.</p> <p>The approach taken in draft report of presenting risk information does not meet the requirements outlined in the Risk Characterization Handbook of transparency, clarity, consistency and reasonableness. Specifically, the audience for this document includes risk managers who will use the quantified cancer risks and non-cancer health hazards to inform the Feasibility Study (FS) and ultimately the Record of Decision (ROD). Another audience for this document is the public who are concerned about potential health impacts from exposures where a statement regarding the degree to which the cancer risks and non-cancer health hazards goals of protection are exceeded is important information.</p> <p>Consistent with the Risk Characterization Handbook (Section 2.3.2), the Risk Assessment Guidance for Superfund Part A (Exhibits 8.2 and 8.3 and Section 8.6 where the last bullet on page 8-25 calls for presenting “the magnitude of the cancer risks and noncancer hazard indices relative to the Superfund site remediation goals in the NCP (e.g., the cancer risk range of 10^{-4} to 10^{-7} and noncancer HI of 1.0;),” and RAGS Part D Tables (Instructions for Table 10 Risk Summary), the text and tables of the main body of the report need to clearly identify the calculated numerical cancer risks and non-cancer health hazards.</p>	<p>The risk summary tables presented in the Executive Summary and Summary and Conclusions will be revised to include the numerical risk and hazard estimates.</p>
3	<p>The text in sections 6.3 and 6.4, entitled “Risk Characterization Results” and “COC Identification” provides no discussion of the risk characterization results and limited discussion of COCs to a couple of examples with pesticides and PAHs in a single paragraph. The text in these sections does not discuss the contribution of dioxins/furans or PCBs to the total risk estimates for this site.</p>	<p>Additional discussion of the relative contributions of the various COPCs will be added.</p>

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	<p>In addition, the relative percent contribution of risk from different contaminants, particularly dioxin TEQ and PCBs, as well as other risk drivers, should be listed in the Executive Summary and the Risk Characterization. For example, on Page ES-2, the last sentence of the paragraph on recreational and worker risks says that the "exceedance is due primarily to TCDD-TEQ." This discussion should be expanded to include other contributors such as dioxins, PCBs and mercury.</p>	
4	<p>The Executive Summary and other parts of the document provide information on two RME individuals, one who consumes all fish species and the other who consumes all fish species with the exception of carp. An assumed fish diet that excludes a type of fish known to be kept and consumed by some anglers at the site, and known to have elevated chemicals of potential concern (COPC) concentrations, does not represent an RME scenario, and should not be presented as such.</p> <p>A mixed diet that excludes carp should be removed from the report entirely, or presented in the uncertainty evaluation as a potential variation on the mixed fish diet that would most significantly alter the mixed diet RME risk estimates (as opposed to variations that remove one of the other species). Alternatively, the text of the uncertainty section can provide information on individuals consuming each species (i.e., cancer risks and non-cancer health hazards), to account for specific preferences. This information can then be compared to the risk range and goal of protection of an HI of 1.</p> <p>In addition, the RME scenario for crab ingestion should include the hepatopancreas along with the muscle and should not be included alongside discussion of a muscle-only diet. Again, any discussion of the changes in the risk estimates by excluding the hepatopancreas should only be included in the uncertainty section.</p> <p>In general, one RME scenario should be presented for each exposure pathway.</p>	<p>The CPG disagrees and maintains there is value in presenting multiple reasonable maximum exposure (RME) scenarios, and does not accept the Region's narrow interpretation that EPA's risk assessment guidance prescribes limiting the RME evaluation to a single scenario. It is known that many LPRSA anglers do not eat carp, which have the highest chemical concentrations of the species sampled. Risk estimates with and without this species would be of interest to the public as well as risk managers. The same applies to a crab diet with and without the more contaminated hepatopancreas, which is consumed by only a fraction of the population. In 2008, CSTAG called for an evaluation of the crab muscle only diet which the Region chose to ignore in its HHRA for the 8-mile FFS-RI. CSTAG recognized the importance of evaluating crab muscle only, because it is the tissue type typically consumed.</p> <p>Therefore, the CPG does not agree to remove the mixed fish diet without carp and the crab muscle only diet entirely from the report. The document will be revised to present these scenarios in the uncertainty analysis as a variation on the RME, along with the single species diets that are already discussed. The implication of alternative diets will also be mentioned in the executive summary and the conclusions of the report.</p>
5	<p>The text continually emphasizes that the assumptions and risk assessment approach are conservative, resulting in overestimates of risks. The document should also acknowledge the potential that the risks and hazards are underestimated i.e., lack of toxicity data for a number of chemicals, use of surrogate data, use of high end values that are not the highest percentile, use of</p>	<p>The Region has demonstrated a pattern of advocating for and favoring overly conservative assumptions in order to generate unrealistic RME scenarios and risk characterizations. Examples include fish and crab ingestion rates, the assumption that 100% of fish and crab consumed comes from</p>

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	average exposure assumptions such as body weight, skin surface area, etc. The information should be presented in a way that recognizes the range of estimates used in the calculation of the cancer risks and non-cancer health hazards.	the LPRSA, and exposure frequencies and times for swimming. Nonetheless, during the revision process, the document will be reviewed to ensure that relevant assumptions and approaches that may lead to underestimating risks and hazards, if any, are acknowledged.
6	<p>Sections 6.5 and 7 and Appendix L of the HHRA misrepresent the concentrations used in the risk calculations as “upper-bound” values. The concentration values used (i.e., 95 percent upper confidence limit of the arithmetic mean) are estimates of the arithmetic average concentration of each contaminant at the site accounting for uncertainties in the data, as accurately described in Section 4.</p> <p>Discussions of the Upper Confidence Limit (UCL) concentration statistic in Section 6.5 and Appendix L should be corrected, the “mean” scenario should be removed, and the “upper-bound” scenario should be correctly labeled as the RME scenario.</p> <p>Discussions of the UCL concentration statistic in Section 7 should be corrected, particularly on pages 7-46 and 7-49, where it is interpreted as a 95th percentile.</p>	<p>The CPG rejects the Region's contention that the BHHRA misrepresents the UCL concentrations used in the background risk calculations by referring to them as upper-bound. The background risk calculations presented in Section 6.5 and Appendix L intentionally provide a risk range based on the simple arithmetic mean and the 95% UCL on the arithmetic mean.</p> <p>Nonetheless, the background risk calculations will be revised to use only the UCL which will be referred to as the RME scenario, and the mean scenario will be removed.</p> <p>The text in Section 7 will be revised to clarify that the 95% UCL is not the same as the 95th percentile.</p>
7	The term “non-cancer hazards” needs to be used consistently in place of non-cancer risks. Non-cancer hazards do not represent a probability of disease as do cancer risks. The use of the term risks for non-cancer health effects confuses the presentation of information and needs to be restated as non-cancer hazards consistently throughout the document.	The term non-cancer risks will be replaced with non-cancer hazards.
8	Throughout the document the terms Chemicals of Potential Concern (COPC) and Chemicals of Concern (COC) are used interchangeably. A determination regarding COCs is finalized at the time of the ROD. Currently, the text provides this information in Section 6.4 but does not clearly indicate that the ROD is the point where the final determination is made. The term COPC should be used in the document and a section in the Risk Characterization should formally identify the COCs pending the finalization of the ROD.	The CPG rejects the Region's characterization of the BHHRA discussed in this comment. As discussed with Region 2 during the June 15, 2015 call, the terms COPC and COC have not been used interchangeably. It is the CPG's understanding that Region 2's comment was intended to convey that the BHHRA should not use the term COC. As requested by Region 2 in the June 19, 2015 letter, the term “COC” will be replaced with “potential COC” throughout the document.
9	The term “target” should be removed from the discussion of the risk range. The goal of the risk assessment is to provide information and not to set a goal of a specific cancer risk or non-cancer hazard. Use of the term “target” appears to suggest a specific risk or hazard goal in the risk assessment. Instead, please use	The report will be revised to use the requested language.

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	<p>the following language:</p> <ul style="list-style-type: none"> a. Any cancer risk above 10^{-4} should be said to "exceed the NCP risk range." b. Any cancer risk between 10^{-4} and 10^{-6} should be said to be "within the NCP risk range." c. Any HI above 1 should be said to "exceed the goal of protection of an HI=1." The qualifier "slightly" should not be used. 	
10	<p>The text regarding the inclusion of the Reasonable Maximum Exposure (RME) and Central Tendency Exposure (CTE) needs to clarify that the RME is the basis for any risk management decisions under the Superfund program. As currently presented, the text suggests decisions may be based on the CTE. RAGS Part A, Chapter 6, (page 6-5) states: Actions at Superfund sites should be based on an estimate of the <u>reasonable maximum exposure (RME)</u> expected to occur under both <u>current</u> and <u>future</u> land- use conditions. The reasonable maximum exposure is defined here as the highest exposure that is reasonably expected to occur at a site. RMEs are estimated for individual pathways.</p> <p>The text in several places appears to concentrate on population risks and hazards. Consistent with Superfund guidance and policies, the goal of the baseline human health risk assessment is to identify cancer risks and non-cancer health hazards for the RME individual.</p> <p>The entire document needs to be reviewed and modified to reflect these comments.</p>	<p>The BHHRA text already references the quote from RAGS stating that Superfund actions are based on the RME (see Section 4.3). The text is consistent with language from the RARC Plan that was provided by Region 2 in its comments on the draft RARC (see Comment 98 of EPA's July 11, 2011 comments). As directed by Region 2 in its July 11, 2011 comments, this language was included in the RARC and has been included in the applicable section of the BHHRA (Section 4.3), including the specific RAGS Part A Chapter 6 quote referenced in this general comment.</p> <p>In its June 12, 2015 letter, the CPG requested that the Region provide specific examples of where in the text population risks and hazards are discussed, as the Region contends in its comment. The CPG's search of the 17-mile BHHRA for the term "population risk" found none. The Region has not responded to this request.</p>
11	<p>Throughout the document, the term "more realistic" is used to discuss either CTE exposures or alternative exposure factors. This term should be deleted. The CTE, or alternative exposure factors, might describe average exposures. However, RME exposures are realistic, albeit they likely apply to a smaller number of individuals.</p>	<p>The CPG disagrees that the term "more realistic" has been used "throughout the document." Region 2 acknowledged this during the June 15, 2015 call. The term "more realistic" is used to describe alternate exposure factors only five times in the Uncertainty Analysis (discussing adult body weight of 80 kg [which is EPA's 2014 revised default adult body weight], swimming exposure times less than 2.6 hours, fish consumption rates less than 34.6 g/day, fraction ingested less than one for crab, and accounting for cooking loss). This is hardly throughout the document.</p> <p>It should be noted that in the risk assessment for the Gowanus Canal, prepared for Region 2 by HDR, CH2M-HILL, and GRB, the uncertainty analysis states on page 8-2</p>

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		<p>[emphasis added]:</p> <p>“Based on the current conditions of the canal, it is likely that this is an overestimate of actual exposure to recreational receptors. Although possible, it is highly unlikely that a recreational receptor would swim in the canal for 26 days per year for 2.6 hours per day. Although the RME scenario indicated a slight risk above USEPA target levels, the CTE scenario (using <u>more realistic</u> but conservative assumptions of an exposure frequency of 13 days per year and an exposure time of 1.3 hours per day) indicated a risk within USEPA acceptable risk levels.” It is unclear to the CPG and possibly to the public why Region 2 is inconsistent and objects to the use of similar language for the LPRSA BHHRA.</p> <p>However, the term will be removed in the limited places where it has been used and replaced, as appropriate, with the term alternate,, plausible, more typical, or site-specific.</p> <p>Additionally, the CPG maintains that many of the Region's directed exposure factors for the RME are not realistic for the LPRSA.</p>
12	<p>Overall, the text requires revisions to concentrate on the main risk drivers with less emphasis on exposure parameters that are not significant drivers. The Uncertainty section also needs to concentrate on the main risk drivers. A table summarizing the main risk drivers and whether they contribute to the over or underestimate of risks/hazards for the main contributors is needed to concentrate on the most significant information. The current presentation provides extraneous information that does not focus on the most important results of the risk assessment. Overall, the risk characterization should focus on those exposures that are the primary risk drivers.</p>	<p>The CPG disagrees with the Region's characterization of the BHHRA text and believes the text appropriately focuses on risk drivers and key issues, and that extensive revisions are not needed nor justified. Region 2's comment suggests a level of simplicity in documentation that belies the complexity of the LPRSA, the extensive data available, and scientific uncertainty on topics relevant to the risk results. The issues discussed in the uncertainty analysis are consistent with RAGS guidance and important to the understanding and interpretation of site risks. As part of revising the document, the uncertainty analysis will be reviewed to identify any potential areas where it can be revised, and a table summarizing key issues and the associated impact on risks/hazards will be added.</p>
13	<p>The treatment of background throughout the report is inappropriate and is not consistent with risk assessment guidance or the more specific guidance on background, “Guidance for Comparing Background and Chemical Concentrations</p>	<p>The CPG disagrees with the Region's contention that the treatment of background in the report is inappropriate or inconsistent with EPA guidance. The OSWER Directive</p>

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	<p>in Soil for CERCLA Sites,” OSWER Dir. 9285.7-41, September 2002., which includes as Appendix B, “The Role of Background in the CERCLA Cleanup Program,” OSWER Dir. 9285.6-07P, May 2002.</p> <p>a) Background should not be discussed throughout the report. It should only be discussed in the risk characterization section, to put things in context. The background data should not be used to mitigate or otherwise detract from the risks posed by the site itself.</p> <p>b) The draft BHHRA did not test any hypothesis of whether site data and background data are the same. Rather, the report contains statements that “background levels of [some chemicals] contribute significantly to LPRSA risks” or “are comparable to LPRSA risks” (p. ES-2) without statistically supporting the statements. Similar statements are made elsewhere in the BHHRA: pp. ES-3, ES-9, ES-11, Section 6.5.2. EPA’s Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites (September 2002, Chapter 5) recommends quantitative statistical approaches for comparing site data to background data. A statistical comparison of site data with background data should be performed before conclusions are made about whether site data exceeds or is comparable to background data, and before attributing specific fractions of the site risk to background (e.g., pages 6-30 through 6-34 of BHHRA). The Background Guidance (p. 3-1) notes “in comparisons with background the parameter of interest is... the amount by which the mean of the distribution of concentrations in potentially impacted areas exceeds the mean of the background distribution.”</p> <p>c) Finally, if you wish to include calculated risks from background fish or sediment concentrations, the background dataset should follow the same rules as the LPRSA dataset (e.g., only accessible sediment samples should be used to calculate the risks for sediment exposure). Note that the contribution of background sediment concentrations to concentrations below the dam should be evaluated in the Remedial Investigation (RI) or FS reports. This evaluation may include a larger set of data than that used for risk comparisons.</p>	<p>9285.7-41 (USEPA 2002), Appendix B (“Policy Considerations for the Application of Background Data in Risk Assessment and Remedy Selection”) states that “the Risk Characterization should include a discussion of elevated background concentrations of COPCs and their contribution to site risks.” The CPG believes the background evaluation approach followed in the BHHRA report (presented in Section 6.5) is consistent with this objective. It is also consistent with the approach used by Region 2 in the revised FFS Appendix E, Section 3.2 Human Health Evaluation of Background Conditions.</p> <p>a. The CPG does not agree that background is discussed throughout the report. Consistent with the 2002 guidance, background and specifically the potential risks posed by background conditions, are appropriately discussed in the risk characterization section. Background is also discussed in the Summary and Conclusions and the Executive Summary to put site risks into context. This is hardly throughout the report.</p> <p>b. The 2002 guidance does not specify that a statistical comparison of site and background data is needed before calculating potential risks from background. Further, Region 2 did not statistically compare site and background before performing background risk calculations in the revised FFS on PCBs, dioxin, and mercury in fish and crab tissue. However, to provide additional information, a statistical comparison of site and background will be added for a subset of COPCs in sediment and tissue.</p> <p>c. The background datasets used in risk calculations will follow the same rules as the LPRSA datasets.</p>

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14	<p>An update to the Superfund Standard Default Exposure Factors was recently published in February 2014. The entire risk assessment should be updated using the new EPA guidance values. However, the value for Exposure Duration should be maintained as 70 years and not changed to 78.8 years based on the 2011 EFH. The basis for this decision is consistency with the toxicity values as outlined in the 2011 EFH Introduction.</p> <p>Please note we do not expect changes in these values to significantly affect the overall calculations of risk for this site.</p>	<p>The exposure factors in the BHHRA will be revised to reflect current guidance, including the Standard Default Exposure Factors published in February 2014 (with corrections in April 2015), and the 2011 version of the Exposure Factors Handbook.</p> <p>As discussed in the June 15, 2015 call with Region 2, the revised exposure factor tables are attached to this RTC.</p>
15	<p>The following general comment relates to the calculation of cancer risks and non-cancer health hazards from PCBs and Dioxins:</p> <p>RAGS Part D Tables 7 through 10, provide calculated cancer risks for total PCBs and dioxin-like PCBs but do not present information on non-dioxin like PCBs or total risks including both dioxin-like and non-dioxin like PCBs. In addition, the non-cancer health hazards associated with dioxin-like PCBs are not calculated.</p> <p>Page ES-5 of the draft BHHRA indicates that the evaluation was based on total PCB including both dioxin-like PCBs with the application of the 2010 Guidance and total PCBs without subtracting out the dioxin-like from the Total. Consistent with EPA's documents titled "Use of Dioxin TEFs in Calculating Dioxin TEQs at CERCLA and RCRA Sites" (2013 Guidance) and the "1996 Reassessment of PCB Cancer" (1996 Guidance), cancer risks and non-cancer hazards should be provided for Total PCBs, dioxin-like PCBs and non-dioxin like PCBs and dioxin TEQ (see Example 4 from the 1996 guidance).</p> <p>A Hazard Quotient should be calculated for dioxin-like PCBs since as stated in the document Use of Dioxin TEFs, "the toxicokinetics and toxicodynamics for all DLCs are similar and act by a common toxic mode of action". Therefore, the calculation of non-cancer HQ for dioxin-like PCBs should be provided in the table and summed with the calculated hazards for non-dioxin like PCBs.</p> <p>The RAGS Part D Tables should provide calculated EPCs and associated cancer risks and non-cancer HQ for dioxin-like and non-dioxin like PCBs, and total PCBs, consistent with the 1996 Guidance – Example 4. Further these calculated risks and non-cancer hazards from the dioxin-like and non-dioxin like PCBs should be combined to calculate the total cancer risks and non-cancer health hazards.</p> <p>The Uncertainty Section of the report may discuss the potential double counting of the cancer risks for the non-dioxin like PCBs indicating the limited knowledge regarding the percent of dioxin-like PCBs in the Aroclor mixtures tested in the animals that were used in the derivation of the Cancer Slope Factor with appropriate citations to the paper by Coglian, V.J. Assessing the Cancer Risks from Environmental PCBs. Environmental Health Perspectives 106(6): 317-323,</p>	<p>The calculation requested by Region 2 involving summing PCB TEQ and non-dioxin-like PCB-specific risks (minus the concentration of dioxin-like PCBs) results in double-counting for both cancer risk and non-cancer hazard.</p> <p>The CPG disagrees that the 2013 Guidance indicates that risks/hazards should be provided for total PCBs, dioxin-like PCBs, and non-dioxin-like PCBs. The 2013 Guidance discusses the calculation of two separate cleanup goals for PCBs: 1) one based on the toxicity of total PCBs (using the IRIS slope factors); and 2) one based on the toxicity of PCB-TEQ (using the TCDD slope factor). There is no mention in the 2013 Guidance of non-dioxin-like PCBs or summing non-dioxin-like PCBs with PCB-TEQ. The approach used in the BHHRA for the LPRSA is entirely consistent with the 2013 Guidance in that two separate toxicological assessments of PCBs are considered. EPA's 2010 TEF guidance also does not discuss non-dioxin-like PCBs or adding these risks to PCB-TEQ; rather PCB-TEQ should be summed with TCDD-TEQ to yield total TEQ. Again, the CPG's BHHRA is consistent with the 2010 TEF guidance. The 1996 Guidance that Region 2 cites is now nearly 20 years old, and does not reflect current science for PCBs. Further, the Example 3 (not 4) in Section 5 of the 1996 Guidance is just that – an example that can be used to provide additional information when congener data are available. This additional information is contained in the CPG's BHHRA in the form of two estimates of PCB cancer risk.</p> <p>Summing the PCB-TEQ risk/hazard with that posed by the non-dioxin-like fraction using toxicity values derived for total</p>

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	<p>1998. In addition, the text in the Uncertainty Section can describe differences between the calculated total PCBs and dioxin-like and non-dioxin-like PCBs (e.g., enhancement of the risks and hazards from the dioxin-like PCBs) as an uncertainty.</p> <p>Example of Presentation of Information:</p> <table><tr><th>COPC</th><th>Cancer Risk</th><th>Non-Cancer HI</th><th>Note</th></tr><tr><td>Total PCBs</td><td>5x10-4</td><td>15</td><td>Presented for information but not included in the calculation</td></tr><tr><td>Dioxin-like PCBs</td><td>1x10-4</td><td>3</td><td></td></tr><tr><td>Non-Dioxin-Like PCBs</td><td>3x10-4</td><td>12</td><td></td></tr><tr><td>Total Dioxin-Like/Non-Dioxin Like PCBs</td><td>4x10-4</td><td>15</td><td>Include this value in the total for all Chemicals</td></tr><tr><td>Dioxin TEQ</td><td>1x10-3</td><td>25</td><td></td></tr></table> <p>The total calculated risks for all chemicals would include dioxin-like PCBS and non-dioxin like PCBs and the Uncertainty Section would discuss whether the analysis found enhancement of the dioxin-like PCBs and the uncertainties associated with the cancer slope factor based on the paper by Cogliano listed above.</p>	COPC	Cancer Risk	Non-Cancer HI	Note	Total PCBs	5x10-4	15	Presented for information but not included in the calculation	Dioxin-like PCBs	1x10-4	3		Non-Dioxin-Like PCBs	3x10-4	12		Total Dioxin-Like/Non-Dioxin Like PCBs	4x10-4	15	Include this value in the total for all Chemicals	Dioxin TEQ	1x10-3	25		<p>PCBs (cancer) and Aroclor 1254 (non-cancer) is not sound science. The approach identified by Region 2 of subtracting the mass of dioxin-like congeners from the total does not resolve double-counting of toxicity, if the CSF and RfD used to evaluate the non-dioxin-like fraction are based on all congeners in the Aroclor mixture. The dioxin-like congeners contribute significantly to both the cancer and non-cancer toxicity of the mixture. Thus, the use of unadjusted total PCB toxicity values (e.g., upper-bound PCB CSF of 2 mg/kg-day¹ or Aroclor 1254 RfD of 2E-05 mg/kg-day) to evaluate the non-dioxin-like PCBs overestimates the risk/hazard of this fraction.</p> <p>The CPG does not agree that the BHHRA needs to be revised to address non-dioxin-like PCBs for cancer or non-cancer effects. However, a discussion of the potential non-cancer hazard of PCB-TEQ, including the application of the TCDD reference dose, will be added to the Uncertainty Evaluation.</p>
COPC	Cancer Risk	Non-Cancer HI	Note																							
Total PCBs	5x10-4	15	Presented for information but not included in the calculation																							
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Dioxin TEQ	1x10-3	25																								
16	<p>The following general comments all relate to PCBs:</p> <p>a. The report needs to be edited to indicate EPA's classification of PCBs as a Probable Human Carcinogen. Any discussion indicating there is no evidence of cancer from exposure to PCBs should be removed. The text should use the language provided under the Classification of Carcinogens section of the PCBs IRIS file. This comment applies primarily to Sections 5.1, 5.6.2.1, and 7.3.2.1, though other instances may appear.</p> <p>The IRIS chemical file for PCBs includes a Weight of Evidence classification for PCBs of Probable Human Carcinogen. This classification, which was made in 1996, was based on human studies that were being updated, and indicated at that time that the currently available evidence was inadequate but suggestive. More recently, the International Agency for Research on Cancer (IARC) classified PCBs as Group 1, Carcinogenic to Humans, based on the conclusions of an IARC convened panel. These conclusions are presented in a paper in The Lancet Oncology, Volume 14, Issue 4, Pages 287 - 288, April 2013. The report was published online on March 15, 2013, and can be found</p>	<p>a. Table 5-2 indicates that PCBs are classified as Class B2 carcinogens. The text will be revised to clarify EPA's classification, and the discussion regarding human carcinogenicity evidence will be limited to the uncertainty evaluation.</p> <p>b. The individual PCB congeners and dioxins/furans were included in the screening tables for completeness. As discussed in the June 15, 2015 call with Region 2, a statement to that effect will be added to the text.</p> <p>c. As discussed in the June 24, 2015 call with Region 2, Table 3-7 will be expanded to include co-eluting PCB congeners by lab/sampling event, and a brief explanation will be added to the report (pending confirmation from Region 2's contractor on this</p>																								

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	<p>at: [HYPERLINK "http://www.iarc.fr/en/media-centre/iarcnews/index1.php?year=2013"].</p> <p>In addition, the National Toxicology Program has classified PCBs as reasonably anticipated to be carcinogenic to humans. This classification can also be provided in the text to represent the range of classifications from different organizations</p> <p>b. The rationale for screening individual PCB congeners and dioxins/furans against respective screening levels should be provided since total PCBs and total dioxin and furan TEQ were already included in Tables 3-8 to 3-10.</p> <p>c. It appears that the co-eluting PCB congener list in Table 3-7 was applied across all sampling events and should not be because co-eluting PCB congeners differ by sampling event. Thus, the same list should not be used for all total PCB calculations. Based on the electronic data received from the CPG in 2012 for task code 12A and analytical data presented in Appendix A, some of the PCB congeners identified as co-eluting list different result values for the individual congeners. For example, in both Appendix A and electronic data file, results for sample 12A-0401-C2AS listed PCB-110 as 0.0211 mg/kg and PCB-115 as 0.000397 mg/kg. PCB- 110 and PCB-115 are listed as co-eluting PCBs on Table 3-7; however, they have two different results and are not identified as being co-eluting PCBs in the electronic data file received for task 12A. Thus, the total PCB concentration cannot be verified since the co-eluting PCBs are different between individual sampling events. Table 3-7 should be revised to include co-eluting PCB congeners for each sampling event.</p> <p>In addition, please use the agreed procedure to identify co-eluting PCB congeners. A qualifier code of "C####" should be included to identify co-eluting PCB congeners in data presentation in Appendix A. Consequently, the subsequent tables listing that "the co-eluting PCB congeners are not shown in the COPC screening tables" should be revised since the co-eluting PCB congeners differ by sampling events.</p>	<p>approach).</p>

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17	List of Acronyms	By spot checking, it is noted that this list is not complete, such as AOC, TERA. Please make sure it is complete.	The acronym list will be reviewed and revised as appropriate.
18	Executive Summary	As noted in the overall comments, the Executive Summary provides comparisons to the risk range established under the NCP without specifically stating the calculated cancer risks and non-cancer health hazards. Tables specifically identifying the calculated cancer risks and non-cancer health hazards along with the main COPCs that contribute to the total risk and hazard should be included, for both the RME and CTE scenarios. In addition, the text of Section ES.1 should include the calculated cancer risks and non-cancer health hazards. Finally, the Executive Summary should focus on those risks above and within the NCP risk range and the non-cancer health hazards above the goal of protection of an HI of 1. Other risks and hazards not meeting these criteria can be briefly summarized in the Risk Characterization portion of the document.	As indicated in the response to Comment 2, the risk summary tables will be revised to include the numerical risk and hazard estimates.
19	Executive Summary	<p>When summarizing risks and hazards, both in the Executive Summary and elsewhere in the document, please use the following guidelines:</p> <ul style="list-style-type: none"> a. Any cancer risk greater than 10^{-4} should be said to "exceed the NCP risk range." b. Any cancer risk between 10^{-4} and 10^{-6} should be said to be "within the NCP risk range." c. Any HI above 1 should be said to "exceed the goal of protection of an HI=1." The qualifier "slightly" should not be used. d. Calculated risks and non-cancer hazards should be specifically stated for both the RME and CTE scenarios. <p>For example, based on these guidelines, we suggest Bullet 1 on Page ES-1 be rewritten as:</p> <p style="padding-left: 40px;">"Based on the reasonable maximum exposure (RME) scenario, the cancer risk to a recreational angler on the LPRSA consuming a mixed species fish diet exceeds the NCP risk range of 10^{-4} to 10^{-6}. The cancer risks to the RME individual are [insert calculated risk] for the adult, insert calculated risk] for the young child, [insert calculated risk] for</p>	<p>As noted in response to Comment 9, the requested change in language will be made. The bullets in the Executive Summary will be revised as suggested.</p> <p>The CPG notes that the Region used the subjective qualifier "much" at the bottom of column 1 (last line) on Page 14 of the April 2014 8-mile Proposed Plan:</p> <p><i>"All of the RME hazards are much [emphasis added] higher than EPA's goal of protection of a HI of less than or equal to 1."</i></p> <p>The Region is requested to explain and clarify when it is appropriate to apply a subjective qualifier to discussions of risks and hazards.</p>

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		<p>the adolescent, and [insert calculated risk] for the young child/adult."</p> <p>Bullet 2 can be rewritten as:</p> <p>"The non-cancer hazards to the RME recreational angler on the LPRSA consuming a mixed species fish diet exceed the goal of protection of a Hazard Index (HI) equal to 1. The non-cancer health hazard is [insert calculated HI] for an adult angler, [insert calculated HI] for an adolescent and [insert calculated HI] for the young child consuming fish caught from the LPRSA."</p>	
20	Executive Summary, Page ES-1	As noted in the overall comments, the 3 rd bullet on Page ES-1 should be deleted.	The third bullet will be revised to note that a mixed fish diet that does not include carp is associated with about four-fold lower risks (see response to comment 4).
21	Executive Summary, Page ES-2	<p>Under crab consumption:</p> <ol style="list-style-type: none"> Language in the first and second bullet should be modified as noted in Specific Comment 19. The 3rd bullet should be deleted. This information can be discussed in the uncertainty section The word slightly should be removed from the 4th bullet. The word slightly should be removed throughout the document as a modifier to the HI calculated. In the 4th bullet, muscle-only results should not be discussed here; they should be discussed in the uncertainty section only. Note that, according to Table 6-6, the CTE non-cancer hazard index for a diet of crab muscle only is 1, not below 1. 	<ol style="list-style-type: none"> The language will be modified. The third bullet will be revised to note that a crab diet that excludes the hepatopancreas is associated with about five to six-fold lower risks. See response to comment 4. The word slightly will be removed and the specific hazard indices will be added. The CPG does not agree to remove the statement. See response to comment 4.
22	Executive Summary, Page ES-2	The section called "Influence of Background Conditions on Risk" should be renamed "Background Evaluation" and the language will need to be revised based on comments contained herein. In addition, a table may more clearly convey the information than text.	The section will be renamed Background Evaluation, and the discussion revised in accordance with responses to other comments. The inclusion of a table to convey information discussed in the text will be considered.
23	Executive	a. At the end of the 3 rd sentence of the 2 nd paragraph, add the	a. The phrase will be added (with the exception

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	Summary, Page ES-4, Section ES.2.2	<p>phrase “though homeless groups have been observed along this stretch of the river.”</p> <p>b. The 2nd paragraph should note the presence of several residential properties on the eastern bank with yards that abut the river, perhaps at the end of the sentence that mentions parks and boathouses above RM 7.</p> <p>c. Please check whether the reference in the paragraph before the bullets should be to the 2009 Problem Formulation Document, not the CSM.</p> <p>d. The last paragraph on this page should highlight that all decisions will be based on Reasonable Maximum Exposures.</p>	<p>of the word “groups”).</p> <p>b. The text will be revised as requested.</p> <p>c. The paragraph references the CSM in the PFD, and the text will be clarified.</p> <p>d. The text will be revised to note that Superfund actions are based on the RME, and RAGS Part A will be added as a reference (USEPA 1989b).</p>
24	Executive Summary, Page ES-7, Table	<p>The table lists exposure to the surface water pathway as incomplete for the adult worker. Please change this to not quantified, and add a footnote stating that adult workers could include fire/rescue squads that may be exposed to the surface water, but their risks would be less than the risks quantified for an adult swimmer.</p> <p>EPA understands this is a departure from the RARC Plan. However, we do receive calls about this exposure pathway from time to time and think it is worth noting in the document.</p>	The text will be revised as requested.
25	Page ES-9, Last sentence	Please add in parentheses “approximately 30 meals of 6 crabs per year” instead of “approximately 170 crabs per year.”	The text will be revised as requested.
26	Page ES-10, Second sub-bullet	Remove the phrase after the semicolon related to carp and replace with “however, a diet that includes any individual fish species was found to exceed both the NCP risk range and the goal of protection of an HI=1 under the RME scenario. Further, a diet that includes any individual fish species was found to be within or exceed the NCP risk range and exceed the goal of protection of an HI=1 under the CTE scenario .	The text will be revised to include a discussion of individual fish species risks, including a note that only carp exceeds the NCP risk range under the CTE scenario. The statement regarding a mixed diet with and without carp will not be removed (see response to comment 4).
27	Page ES-11, Last sentence	This sentence should be deleted. It is not appropriate here (“The contribution of background....”).	The sentence will be deleted.
28	Page 1-1, Section 1.0,	It is unclear why risk management guidance is identified in addition to the risk assessment guidance listed in first paragraph. The risk	The text in this paragraph is equivalent to the text in the RARC Plan in the second paragraph on page 1,

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	2 nd Paragraph	assessment should inform the risk management decision and inclusion of this risk management guidance is not appropriate.	with the same risk management guidance documents referenced. The references identify to the risk manager that the risk assessment was conducted with the goal of providing the information consistent with the guidelines on how the risk manager makes decisions. The text will not be revised.
29	Chapter 1. Page 1-3	<p>The following updates are needed:</p> <ul style="list-style-type: none"> • ProUCL 5.0 is the current version of the software and should be added to the bulleted list on this page. • Child-specific Exposure Factors Handbook (USEPA 2008b) was replaced with the 2011 version of the Exposure Factors Handbook (2011 EFH), though all values for the child remain the same. All references to this document should be updated throughout the report to reflect EFH 2011. • Regional screening levels were updated in 2015 and require updating to reflect the latest version expected to be available in May and November. • As noted in the general comments, updated exposure factors were published in February 2014 by OSWER and should be used, though exposure duration should be maintained at 70 years for consistency with the toxicity values. Also note, the surface area factors for adults and children were recently updated after the February 2014 publication, and these values will need to be updated in the text and tables as well. 	<p>The text will be revised as follows:</p> <ul style="list-style-type: none"> • The ProUCL 5.0 reference will be added. • The bulleted reference to the Child Exposure Factor Handbook will be removed, and references to this 2008 guidance will be updated to the 2011 EFH throughout the report. • The RSLs will be updated to those published in June 2015. • See response to comment 14 and the tables provided to Region 2 with the updated information.
30	Page 2-1, Section 2.1	Remove the last sentence of the 2 nd paragraph. This is a CERCLA risk assessment and the statement is not necessary.	The last sentence will be removed.
31	Page 2-2, Section 2.1.1, 1 st Paragraph	References to the LPRSA being part of the Diamond Alkali site are fine, but the first paragraph should not focus solely or even primarily on the upland portion of the site. The discussion of the upland facility should be condensed and more discussion of the contributions to the 17 miles should be included, potentially in the third paragraph. References to the operable units should be omitted.	The text will be revised to be consistent with the RI.

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32	Page 2-2, Section 2.1.1, 2 nd Paragraph	Update the discussion to include information regarding the removal action at RM 10.9.	The discussion will be updated to include the removal action at RM 10.9.
33	Page 2-2, Section 2.1.1, 3 rd Paragraph	<ul style="list-style-type: none"> a. The text here mentions only sediment chemistry data for the LPRSA and sediment, surface water and tissue data for areas outside the LPRSA. The presence of contaminants in surface water and tissue samples from the LPRSA should also be noted. b. Briefly expand the discussion to include some description of the types of discharges that have contributed to the presence of other contaminants in the river (i.e., there are many facilities along the river that have contributed contamination). c. The last sentence of this paragraph should also be deleted. 	<ul style="list-style-type: none"> a. The discussion will be expanded to note the presence of contaminants in surface water and tissue of the LPRSA. b. The discussion will be revised to be consistent with the RI. c. This sentence speaks to regional conditions that are relevant to the discussion of Site Background. The sentence will not be removed, and a reference to the RI will be added.
34	Page 2-3, Section 2.2, Table	Please verify that the referenced source of the land use data is the most up to date available.	The source will be reviewed and if necessary, updates will be made.
35	Page 2-3, Section 2.2.1	The section about the upper river (Section 2.2.2) mentions master plans. Please also cite to master plans for the municipalities in this portion of the river.	The CPG notes for the benefit of the Region that the text in this section is directed language from Region 2 for the RARC. References to master plans in this portion of the river will be added (see response to comment 36).
36	Pages 2-3 to 2-4, Section 2.2.2	The master plans mentioned in this section should be referenced in the correct portion of the river. For example, reference to actions near the Sherwin Williams site should be discussed in Section 2.2.1.	The paragraph describing master plans and redevelopment along the waterfront will be placed under a new subsection, 2.2.3 Redevelopment on the LPRSA.
37	Page 2-3, Section 2.2.1	Please add language to the end of the last paragraph of this section mentioning that while access is limited, homeless groups have been observed and docks and other potential access pathways are present along this stretch of the river from which workers may fish and/or crab.	The text will be revised (with the exception of the word "groups".
38	Pages 2-4 to	The designated uses for all water classified by NJDEP as SE3 are ([The CPG notes for the benefit of the Region that

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	2-5, Section 2.3	<p>HYPERLINK "http://www.nj.gov/dep/rules/rules/njac7_9b.pdf" \h]):</p> <ol style="list-style-type: none"> 1. Secondary contact recreation; 2. Maintenance and migration of fish populations; 3. Migration of diadromous fish; 4. Maintenance of wildlife; and 5. Any other reasonable uses. <p>"Secondary contact recreation" means recreational activities where the probability of water ingestion is minimal and includes, but is not limited to, boating and fishing. The definition may include swimming in the future.</p> <p>The NJ reference provided above should also be used to further describe definitions for FW2-NT and SE-2 classified waters.</p>	<p>description of the NJ surface water classifications was language provided by Region 2 for the RARC, and is consistent with the language from the RARC. The NJ reference to the state's water quality rules [[HYPERLINK "http://www.nj.gov/dep/rules/rules/njac7_9b.pdf" \h]] will be added to the first sentence.</p>
39	Pages 2-4 to 2-6, Section 2.3	<ol style="list-style-type: none"> a. The general statement in the second paragraph on page 2-5 (and throughout the document including section 4.1) that "Under current conditions and in the reasonably foreseeable future, recreational activities generally involve those with low potential for direct contact with river sediment and surface water" should be revised. As per the RARC, all of the exposure pathways are currently complete, and local and municipal plans to increase access to the river will likely increase the number of individuals utilizing the river in the future. b. In addition to sculling activities, this section notes that use of canoes and kayaks are occasionally observed. Please also note the ongoing development of a National Park Service water trail from upper reaches of this river, down to Newark Bay (Lower Passaic Canoe and Kayak Trail Action Plan, 2007, National Park Service). c. Remove or revise last sentence of this section which states: "The LPR surveys indicated that potential consumption of LPRSA fish and/or crab by local anglers is limited." 	<ol style="list-style-type: none"> a. The first sentence in the paragraph will be removed. b. The status of the canoe and kayak trail described in the 2007 action plan (and already noted in Section 4.3.4 of the document) will be mentioned in the revised text of Section 2.3. c. The sentence will be removed.
40	Page 2-5, 2 nd	Please revise and combine the 3 rd and 4 th sentences of this	The third sentence of the paragraph notes that this stretch of the river frequently does not meet the

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	Full paragraph	<p>paragraph as follows:</p> <p>Although the state's classification of the freshwater portion of the river (from the confluence with Second River to Dundee Dam) includes swimming as a designated use, there are currently no public beaches or designated swimming areas on the river. As such, the occurrence of swimming under current conditions is expected to be limited.</p>	<p>pathogen standards associated with the state's classification. This statement is in the RARC under the discussion of the Swimmer receptor (Section 3.3.4.2) and provides relevant perspective on the exposure setting. The fourth sentence will be revised as requested, with the addition at the end, "nor are any identified in redevelopment plans." The new sentence requested will be added with the exception of "under current conditions."</p> <p>The text will be revised as follows:</p> <p>Although the state's classification of the freshwater portion of the river (from the confluence with Second River to Dundee Dam) includes swimming as a designated use, this stretch of the river frequently does not meet the pathogen standards associated with this classification (NJHDG 2012). There are no public beaches or designated swimming areas on the river, nor are any identified in redevelopment plans. No swimming was observed during a year-long Creel/Angler Survey (CAS) conducted by the CPG (discussed in Section 2.3.1.1), or during the numerous sampling events completed as part of the remedial investigation at different times of the year. As such, the occurrence of swimming is expected to be limited.</p>
41	Page 2-6, Section 2.3.1, Footnote 9	<p>The potential exists that individuals may travel to fish in both Newark Bay and the LPRSA. In addition, fish move within this system. As such, the use of the Burger 2002 survey is appropriate and can be considered site specific.</p>	<p>The fact that anglers may fish in both systems and that select fish species move within the two systems is not a sound basis for considering the Burger 2002 survey to be site-specific. There are differences between the two water bodies as CPG has previously documented, and it is more accurate to consider it a regional survey. No change to the text will be made in response to this comment.</p>

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42	Pages 2-7 to 2-8, Section 2.3.1.1	<p>This section needs to be revised to reflect the facts that EPA did not approve the work plan for this survey and the results of the survey have not been published or made fully available to EPA for review. Throughout the document, references to the survey can be made anecdotally (i.e., people were observed fishing), but not quantitatively. In addition, the study description should briefly discuss the uncertainties associated with this survey.</p> <p>Please send us revised language for review prior to finalizing the next draft.</p>	<p>In 2009, the Region declined CPG's invitation to participate in a creel/angler survey (CAS) of the LPRSA (11/12/2009 email from Walter Mugdan to Geoff Grubbs). In 2011, the Region also declined CPG's invitation to participate in the development of the peer review charge convened by Toxicology Excellence in Risk Assessment (TERA) (2/14/2011 letter from Walter Mugdan to Rob Law). As a courtesy, the CPG provided Region 2 with a copy of the final CAS Work Plan in November 2011.</p> <p>The CPG disagrees that Section 2.3.1.1 needs to be revised to reflect that the Region did not approve the CPG's work plan. Region 2 did not approve the work plans for the two surveys used to derive the Region's fish and crab consumption rates for the BHHRA, or the other regional angler surveys discussed in Section 2.3.1. As discussed in the June 24, 2015 call with Region 2, the results of the survey are documented in the CAS Data Report, which was made available to the Region in August 2014, as part of the CPG's FFS comments.</p> <p>The CPG disagrees that Section 2.3.1.1 needs to be revised to reference the CAS only anecdotally. Other angler surveys are discussed quantitatively in Section 2.3.1. Based on the Region's July 15, 2015 letter to the CPG, Region 2 needs additional information and/or clarification on the CAS; the CPG will work with the Region to provide this information.</p>
43	Page 3-1, Section 3.1, Second paragraph, 1 st sentence	Provide a reference to the state validation guidelines mentioned in the text, with appropriate citation.	The reference and applicable citations will be included in the revised report.
44	Page 3-2, Section 3.1.1	Language needs to be added to the discussion of accessible sediments. Concentrations of contaminants in sediment that meet the definition of accessible sediment will change over time. A brief	A discussion of the concentrations of key COPCs in nearby sediment samples that are not identified as accessible per the approved definition in the PFD will

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		<p>comparison of concentrations in the 143 samples used to calculate Exposure Point Concentrations (EPCs) should be made to the surrounding sediment concentrations, both horizontally and vertically. Reference to other documents where this issue is explored in more detail (such as modeling reports and the RI) can be made. This discussion can be included here and/or in the uncertainty section.</p> <p>Please modify the last sentence of the paragraph after the bullets in this section as follows, "These areas were excluded because the accessible sediment has been dredged and capped or filled, thereby interrupting the exposure pathway."</p>	<p>be added to the uncertainty evaluation.</p> <p>The last sentence of the paragraph will be revised as requested.</p>
45	Page 3-2. Section 3.1.1. Paragraph 3.	Indicate how the data from the supplemental sampling will be incorporated into the final report.	The supplemental data for sediment and surface water will be incorporated into the summary statistics, COPC selection, EPCs, and risk calculations using the same methods used for the datasets included in the BHHRA.
46	Page 3-2 through 3-3, Section 3.1.1	<p>EPA would like to complete a thorough review of all samples used in the draft HHRA. As such, please provide more details plus the excel table(s) showing the data used. This is not necessarily for inclusion in the report, but rather to aid in our review.</p> <p>These tables should include the SSP2 and surface water results that are now available, along with an updated list/count of samples used, updated data summary tables (such as Table 3.8) and an updated list of COPCs (if necessary).</p> <p>Further, the revised report should clearly list in figures and tables which samples are being used and in which sections of the river they are located.</p>	<p>As agreed on the June 15, 2015 call with Region 2, the excel version of the Tables in Appendix A will be included with the revised draft of the BHHRA submitted to EPA.</p> <p>The tables (both excel and Appendix A) will include the SSP2 and additional surface water samples. Updated counts and lists of samples will be included.</p> <p>The CPG notes for the benefit of the Region that Tables 3-1 through 3-6 clearly identify which samples were included in the BHHRA, and Tables 3-2, 3-4 and 3-6 note the River Mile or reach where the sample was collected. Complementary figures also clearly present where samples were collected. In order to aid in the review of the sediment and surface water tables, sample lists will be organized by River Mile, and the sediment table revised to indicate the applicable river segment for each sample. The text and tables will be revised to reflect updated location and sample counts and COPC lists (if necessary). If Region 2 believes other information is missing, the</p>

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			CPG requests clarification.
47	Page 3-5, Section 3.1.3	The discussion of alternate fish species should explain why the QAPP included alternates.	The explanation will be added.
48	Pages 3-6 to 3-7, Section 3.2.1	<ul style="list-style-type: none"> a. A description of the treatment of rejected data should be added to this section. b. Consistent with RAGS Part D a work sheet describing the QA/QC of data and its usability for the BHHRA should be provided. c. The text describing the evaluation of Polycyclic Aromatic Hydrocarbons (PAHs) should use the term "relative potency factors" and not Toxicity Equivalency Factors (TEFs). The process used for deriving TEFs and the underlying science are significantly different from Relative Potency Factors (RPFs). EPA understands that the draft final version of the Data Usability Memo (dated 5/15/2014) uses the TEF language; this was an oversight on our part and should be corrected in the final document. 	<ul style="list-style-type: none"> a. The description will be added. b. The data were validated in a manner compliant with the current UFP QAPPs. Summaries of the data usability were provided in the RI/FS reports, all the data validation memos for each task were provided, and a complete MEDD compliant with Region 2 requirements containing all the data with validation qualifiers was provided. Therefore, the information included in the form has in fact been provided to Region 2. However, the work sheet will be provided and will include references to the previously submitted information. c. TEF will be replaced with RPF for PAHs.
49	Page 3-8, Section 3.3.1	The reference to Risk Assessment Guidance for Superfund, Part A should be USEPA 1989b and not USEPA 1989.	The revision will be made.
50	Page 3-8, Section 3.3, Point 4	<p>The RAGS Part D Table 2 series will need to be evaluated to reflect the latest Regional Screening Levels at the time the document is finalized.</p> <p>Attached are surrogate values from the Superfund Technical Support Center. The text will need to be updated to reflect these values and tables will need to be updated to reflect the recommendations from STSC. The uncertainties will need to be addressed in the Uncertainty Section of the report.</p>	The screening levels will be updated to the currently available June 2015 RSLs. The surrogates will be updated as recommended by STSC.
51	Page 3-9,	Change the phrase at the end of the last sentence of the 2 nd paragraph of this section to state, "which is higher than the	The phrase is taken from the RARC Plan (Appendix

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	Section 3.3.4	consumption rate used for the LPRSA risk calculations.”	A, Section 3.3.3). The phrase will not be revised.
52	Page 3-10, Section 3.4	<p>a. The text needs to clarify whether inorganic arsenic was maintained as a COPC for crabs.</p> <p>b. The discussion of removal of chemicals based on 5% or less of samples requires clarification. If a chemical was detected above the screening level in greater than 5% of samples then it should be retained as a COPC.</p> <p>c. The last bullet should be updated to reflect the new screening level of 0.24 mg/kg.</p>	<p>a. The text already states that “(...inorganic arsenic is a COPC in the three crab tissue types).” [See first full paragraph, second sentence.]</p> <p>b. This comment is unclear; chemicals detected in 5% or more samples with at least one result above the screening level were retained as COPCs. Chemicals with a frequency of detection (FOD) below 5% were not retained as COPCs provided reporting limits were below the screening level in at least 90% of samples. Chemicals with a FOD below 5% with reporting limits above the screening level in more than 10% of samples were discussed in the uncertainty evaluation. These steps are consistent with the COPC selection process laid out in Appendix A of the RARC. The text will be reviewed and revised, if necessary, to clarify the treatment of chemicals with a FOD below 5%.</p> <p>c. The screening level will be updated.</p>
53	Page 3-11, Section 3.4, 2 nd paragraph, 3 rd bullet	<p>COPCs for fish tissue differ by species. This approach is appropriate for estimating risks for a single-species diet. However, the same set of COPCs should be used across species for the purposes of EPC calculation for mixed diets.</p> <p>From the tables in Appendix H, it appears that EPCs were not actually calculated for the mixed diets. Rather, risks were calculated by species including a diet fraction factor of 25% or 20% in the exposure equations for each species. So if a COPC was not identified for that fish species it was not included in the risk estimate for that portion of the diet, or basically had an assumed concentration of zero in that portion of the diet. Since the concentration in that species could have been just below the risk screening level, the approach taken in the HHRA underestimates</p>	<p>As agreed in the June 24, 2015 call with Region 2, a uniform COPC list will be used across fish species for the mixed diet scenario. EPCs will be derived for each individual species and the mixed diet EPC will be derived by multiplying each EPC by 20% (the fraction of assumed diet for each of the five species included) and summing the fractions. A detected chemical identified as a COPC for at least one species will be included as a mixed diet COPC for other species where it is detected. As agreed with Region 2 during the July 29, 2015 call, if a COPC is not detected in a given species, it will be included as zero in the EPC sum.</p> <p>The CPG notes for the benefit of the Region that the</p>

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		<p>the risks associated with mixed fish diets.</p> <p>Across all fish species, 27 COPCs were identified. Only eight of them were COPCs for all species (as shown in Table 3-12). These eight COPCs included the HHRA risk drivers (e.g., PCDDs/PCDFs, PCBs, dieldrin, methyl mercury) so the most significant risks in the HHRA were not impacted by this issue. However, additional COCs may be identified if the other 19 COPCs are evaluated for all species.</p>	<p>approach used in the risk assessment for the Gowanus Canal, which was prepared for Region 2 by its contractors, was the same as that used for the LPRSA BHHRA. For the Gowanus HHRA, COPC selection was performed on separate summary statistics for striped bass, white perch, and eel. EPCs were derived for the specific set of COPCs for each species. Potential risks were calculated for each species, based on species-specific diet fractions of 0.47 (striped bass), 0.09 (white perch), and 0.44 (eel). The potential risks and hazards for each species were summed to obtain the total potential fish risk and hazard. Region 2 is arbitrarily applying inconsistent approaches for HHRAs within the Region.</p>
54	Page 3-11, Last paragraph	Please delete this paragraph.	<p>The paragraph discusses the identification of tissue COPCs that were not identified as COPCs for sediment or surface water, but were carried through the risk assessment (see also comment 174 which requests the addition of certain chemicals to the table discussed in this paragraph). The first three sentences of this paragraph will be retained.</p>
55	Pages 4-1 to 4-5, Section 4.1	<p>The following language from the RARC should be incorporated into this section:</p> <p style="padding-left: 40px;">In accordance with USEPA Guidance (USEPA 1989b, USEPA 2001b), the scenarios and exposure parameter assumptions are intended to capture exposures under both current and future site conditions. All of the exposure pathways are currently complete. While expected improvements to the river and shoreline will likely increase the number of individuals utilizing the river, the exposure frequency and duration for some individuals already utilizing the river will not likely increase. As such, the use of combined current/future exposure assumptions is appropriate.</p> <p>In addition, the entire document should be reviewed for consistency with this approach.</p>	<p>This language is already presented in the text (Section 4.3, Receptor and Chemical-Specific Exposure Parameters) in the same section where it is found in the RARC Plan (see Section 3.3.4 of the RARC, Receptor and Chemical-Specific Exposure Parameters). No change to the text will be made.</p>

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56	Page 4-2, Section 4.1, Last paragraph	Please remove the 2 nd and 3 rd sentences from this paragraph. Provide a listing of the latest land use guidance references. References are available at [HYPERLINK "http://www.epa.gov/superfund/programs/recycle/pdf/reusedirective.pdf" \h].	The text will be revised.
57	Page 4-5, Table	Under Current/Future Angler, young children are only consuming fish tissue, however, in Section 4.3.1 the young child is assumed to consume fish and/or crab. Please reconcile.	The table on page 4-5 will be revised to indicate that the young child is assumed to consume fish or crab.
58	Page 4-8, Section 4.2.2, second equation	Change the formula for "t*" from "2.4t" to "2.4T"	The change will be made.
59	Page 4-9, Section 4.3	At the end of the 2 nd paragraph, the text should clarify that the RME individual is the basis for decisions under the NCP.	The text in this section is consistent with language in the RARC Plan (see Section 3.3.4 of RARC), including the clarification that the Superfund actions are based on the RME. No revision will be made
60	Page 4-10, Section 4.3.1	The discussion regarding exposures through fish/crab ingestion in the lower 4 miles should include the potential that workers on commercial/industrial properties may fish/crab from the locations.	The Region is requested to provide documentation and citations that workers in the lower 4 miles may fish/crab at the location where they work.
61	Page 4-11, Section 4.3.1, 2 nd paragraph	Add "(adolescent and adult only)" to the end of second and third bullets since exposure of a young child angler to sediment and surface water is not evaluated.	The requested change will be made.
62	Page 4-11, Section 4.3.2	Please delete the second to last sentence on the page ("Any swimming in the river is likely to be..."). This is speculation.	The sentence will be deleted.
63	Page 4-14, Section 2 nd paragraph, 3 rd sentence	To be consistent with the rest of the BHHRA document, please change the sentence to "...fish ingestion rates for the RME adult based on data from Burger (2002) (37.3 g/day) and Connelly et al. (1992) (31.9 g/day)..."	The requested change will be made.
64	Pages 4-13 to 4-15, Section	Reference to the Child Specific Exposure Factors Handbook should be replaced with a reference to the 2011 Exposure Factors	See responses to comments 14 and 29, and the tables documenting the updates (attached to this

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	4.3.6.1	<p>Handbook. The 2011 document replaced the Child Specific EFH.</p> <p>The descriptions of the two surveys should consistently use the term "Newark Bay Complex" and not just "Newark Bay".</p> <p>The text regarding the study by Ray et al. (2007b) should also acknowledge the Letters to the Editor written by EPA regarding the limitations of this study and why EPA determined not to evaluate the values derived from this study. Further, the decision regarding inclusion of the Ray et al. study provided in the February 2012 decision resolving the dispute should also be acknowledged here. The text needs to clarify that decisions under Superfund are based on exposures to the RME individual and are not population based.</p>	<p>RTC).</p> <p>The survey description will be revised to refer to Newark Bay Complex (please see response to comment 41).</p> <p>Per Region 2's June 19, 2015 letter, this comment (referencing Letters to the Editor) will be disregarded.</p> <p>The text (first paragraph of Section 4.3) already states that Superfund actions are based on the RME (see response to comment 59).</p> <p>The CPG maintains there is value in understanding population exposures and risks, particularly when the fraction of the population exposed at RME rates is very small in comparison to the entire population. However, as directed by Region 2, population risks are not discussed in the BHHRA (see response to comment 10).</p>
65	Page 4-15, Section 4.3.6.2, Footnote 26.	This footnote should be deleted. We do not have adequate data on fish populations to make this determination. Further, since human health risk assessments evaluate the individual, not populations, there only needs to be enough fish to support the RME individual's consumption rate.	Footnote 26 will be deleted.
66	Page 4-16, Section 4.3.6.3	Include further information regarding the reasons for not adjusting the cooking loss value for contaminants. Specifically, the text should indicate the potential for individuals to consume pan drippings in sauces and other preparations.	The text will be revised to note that the assumption of zero loss accounts for the potential that individuals may consume pan drippings in sauces and other preparations.
67	Page 4-18, Section 4.3.6.6	Please remove this section. The information is covered elsewhere in the report.	Section 4.3.6.6 will be removed.
68	Pages 4-19 to 4-20, Section 4.3.7.3	The skin surface area for the young child will need to be further evaluated based on the updates to EFH 2011 and also the updated Exposure Factors provided in OSWER Directive 9200.1-120.	See responses to comments 14 and 29, and the tables documenting the updates.
69	Page 4-21,	a. As noted previously, reference to the Child Specific Exposure Factors Handbook should be replaced with a reference to the	a. The reference in this section will be updated

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	Section 4.3.7.4	2011 Exposure Factors Handbook. The 2011 document replaced the Child Specific EFH. b. EPA's Dermal Guidance should also be listed as a reference in this section.	to the 2011 EFH. b. EPA's dermal guidance (USEPA 2004b) is already referenced in this section. The source of adherence factor for the adult will be revised from the 1997 EFH to EPA's Dermal Guidance (USEPA 2004b).
70	Page 4-23, Tables	Please define "na" on the two tables on this page.	na will be defined.
71	Page 4-25, Section 4.3.8, 3 rd bullet	Revise the sentence from "Child (ages 1 to 6 years,...)" to "Young child (ages 1 to 6 years,...)"	The sentence will be revised to state Young child. In addition, the age range will be clarified as 1<7 years, as the receptor is assumed to range in age from the 1 st birthday to the day before the 7 th birthday.
72	Page 4-27, Section 4.3.10.2	The text should clarify the differences between oral absorption factor and relative bioavailability. The text needs to resolve potential overlaps between the equations provided on page 4-6 and the text provided here.	The text will be clarified.
73	Pages 4-28 to 4-29, Section 4.4.1	When the SSP2 data is incorporated into the risk assessment, please use the most current version of ProUCL to update the UCL calculations, both for the sitewide and river segment accessible surface sediments. If any other data sets require recalculation of UCLs, then the most current version of ProUCL should similarly be used. Please note that Version 5.0 is the most current, and the add-on to address dioxin congeners should be used.	ProUCL Version 5.0 and the EPA's dioxin calculator will be used to derive the updated EPCs for sediment and surface water (based on the addition of SSP2 surface sediment and three additional rounds of chemical water column monitoring data to the BHHRA data set).
74	Page 4-30, Section 4.2	In addition to a site wide evaluation (i.e., assuming contact throughout the LPRSA), sediment exposures were evaluated on a refined spatial scale, dividing the river into six three-mile segments. The division of the river into these specific segments is not directly linked to exposure patterns, and other segment divisions could have been selected. The text should note this. In addition, some discussion is warranted in the Uncertainty Evaluation about the degree to which the segment definitions	Exposure patterns were considered in the division of the river into the six three-mile segments, as stated in the last sentence of the second paragraph on page 4-29, "The basis for the six segments includes consideration of land use, shoreline type, access, and the primary types of human activities that take place." The text will be revised to note that other segment divisions could be used, and the Uncertainty Evaluation will note the potential impact of alternative

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		impact risk estimates.	divisions on risk estimates. The CPG notes that the April 2014 FFS-RI treated the lower eight miles of the LPRSA as a single exposure area.
75	Page 4-31, Section 4.4.3	Please provide the sample list used in the RM 6-9 east bank calculation.	Table 3-2 provides the river mile for each sample; the table will be re-organized by river mile and the specific samples used in the RM 6-9 east bank calculation will be listed in the revised text.
76	Section 4.4.4.1, Page 4-31	The document references a high 2,3,7,8-TCDD surface water result that was identified as an outlier and removed from the data set considered in the BHHRA. The location and basis for removal of the sample result as potentially representative of surface water quality in the river should be further discussed and evaluated.	The location of the data point will be included in the revised text. Further clarification regarding the basis for removal of the sample will be added to the text.
77	Pages 4-33 to 4-34, Section 4.4.5.1, First Sentence	The text summarizes total numbers of organisms by species across the 2009-2010 surveys, but the pie charts summarize data from separate surveys. Please add a pie chart that summarizes relative abundance across all surveys. It should be noted in this Section that striped bass is a non-resident species that spends only a part of its time in the LPRSA and, for this reason, striped bass were not sampled for the tissue chemistry program.	A pie chart that summarizes relative abundance across both surveys will be added. The text will be revised to note that striped bass are a non-resident species that spends only a part of its time in the LPRSA, and therefore, was not sampled for tissue chemistry.
78	Pages 4-33 and 4-34, Pie Charts	a. Species in the figure and legend are color coded. However, it is very difficult to match the color for different species. For clarity and easy identification it is suggested that the number of each species caught be also listed on the legend, since the numbers are labeled on the figure. This comment applies to figures on both pages. b. Please remove the blue crab from the pie charts, as these are not pertinent to the relative abundance of fish species and were evaluated separately from fish in the BHHRA.	a. The number of each species will be added to the legend. b. Blue crab will be removed from the pie charts. The number of crab caught in each survey will be presented in Section 4.4.6 (EPCs for Crab Tissue).
79	Page 4-34,	Please add a sentence stating that any species preferences	A statement will be added to indicate there is

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	Section 4.4.5.2	exhibited on this river have a high degree of uncertainty because of the contamination and the existence of a do-not-fish advisory.	uncertainty in species preferences. However, it is speculative to state that species preferences exhibited on the river are highly uncertain because of the contamination and the advisory. The species kept and/or targeted by LPRSA anglers are consistent with those reported for other regional water bodies, including the Delaware River (Faulds et al. 2004) and New York state rivers (Connelly et al. 1992).
80	Page 4-34 and 4-35, Section 4.4.5.3	As noted in the general comments, carp must be included in any mixed-fish diet calculation. Using a mixed fish diet comprised of equal fractions (20%) of each of 5 species evaluated is a reasonable approximation given the inherent uncertainty with the information related to this issue, though other approaches could have been selected (for example, one based on relative abundance). However, a more detailed evaluation of the impacts of this assumption in the uncertainty section is needed.	The CPG reminds the Region that the June 2014 BHHRA includes carp in a mixed fish RME scenario. A discussion of the impact of the assumption of equal fractions will be added to the uncertainty evaluation.
81	Page 4-35, Section 4.4.5.3	Based on information presented later in the report (e.g., page 7-23, third paragraph), smallmouth bass fillet data were actually combined with largemouth bass fillet data to calculate a largemouth/smallmouth bass EPC in the BHHRA. This information should be clearly presented in Section 4.4.5 (EPCs for Fish Tissue).	The text will be clarified.
82	Page 4-35, Section 4.4.5.3, last sentence	Mixed fish diet EPC values should be calculated for a single set of COPCs across species. Risk calculation tables in the BHHRA would be simplified by presenting a single set of EPCs for the mixed diet rather than by repeating COPCs separately for each fish species in that diet.	See response to comment 53.
83	Page 4-35, Section 4.4.6	The RME for crab ingestion based on a combined muscle and hepatopancreas approach is well supported by the knowledge base that is currently available. All discussion of a muscle-only diet should be removed from this section and confined to the uncertainty section.	See response to comment 4.
84	Page 5-2,	The first paragraph of this section can be retained, but the rest should be deleted. Reference can be provided to EPA's Cancer	The second, third, and fourth paragraphs of Section 5.1 will be moved to the uncertainty evaluation; these

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	Section 5.1	Guidelines and RfD/RfC methodology, as well as IRIS, for further details regarding the approach to developing dose-response relationships.	paragraphs present relevant information on uncertainties in dose-response relationships. The first paragraph of Section 5.1 will be merged with Section 5.2, (Sources of Toxicity Data), and references to the relevant guidance will be added. The subsequent subsections in Section 5.0 will be renumbered.
85	Page 5-3, Section 5.2	<p>The discussion of updates to the IRIS program should reflect the current IRIS process outlined on the webpage [HYPERLINK "http://www.epa.gov/iris" \h]. Specifically, this section of the IRIS website should be referenced [HYPERLINK "http://www.epa.gov/iris/process.htm" \h]to explain the process for evaluating chemicals and the discussion of the monthly update should be removed.</p> <p>The Verification Workgroup was disbanded a number of years ago and reference to this group should be removed from the text.</p>	The discussion of the IRIS program updates will be revised to reflect the current process, and the IRIS website will be added.
86	Pages 5-2 to 5-5, Section 5.2, and Related Sections	<p>a. The RSL Table is not EPA guidance or guideline or policy and should not be used as the basis for selecting toxicity values.</p> <p>b. The discussion of TCDD needs to acknowledge other toxicity values such as HEAST, the 1986 HAD value for dioxins, and other values provided on the RS Q and A document, Question #44.</p> <p>The 1996 reassessment of PCB toxicity, an externally reviewed document, identified a slope factor of 150,000 mg/kg-day and this value should be used in the calculation of risks for both dioxin-like PCBs and TCDD TEQs. The value of 150,000 mg/kg-day is listed on page 63 of the 1996 reassessment of PCB cancer toxicity. The text should also refer the reader to the Uncertainty Discussion regarding the range of toxicity values for dioxin.</p> <p>Please note that EPA is aware that draft versions of Tables 5-1 and 5-2 were sent to us for review on 2/7/2014. These tables were discussed during the 3/6/2014 EPA-PA-CPG Technical Coordination Meeting.</p> <p>During that meeting, EPA recommended the use of 150,000 mg/kg- day for the slope factor rather than 130,000 mg/kg-day, as captured in the meeting minutes sent to the CPG via email on</p>	<p>a. Comment noted.</p> <p>b. The CPG notes for the benefit of the Region that Section 7.3.6.1 of the uncertainty evaluation discusses other toxicity values for TCDD, including the values cited in the Question #44 of the RSL Frequently Asked Questions (FAQ). The text will be revised to include a reference to that section of the report.</p> <p>Pursuant to the Region's direction, the TCDD slope factor of 150,000 per mg/kg-day from HEAST (USEPA 1997b) will be used.</p> <p>Surrogates will be updated per the recommendations of STSC, and the last paragraph of Section 5.2 will be removed.</p> <p>c. The discussion of uncertainty factors will be revised to note that values range from 1 to 10, and a reference to the 2002 report will be added.</p>

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		<p>3/26/2014.</p> <p>Update the toxicity values to indicate that recommendations for surrogates provided by Superfund Technical Support Center provided by EPA (attached). Accordingly, the last paragraph of this section can be deleted.</p> <p>c. The discussion of Uncertainty Factors should indicate the values range from 1 to 10 especially and reference the December 2002 report titled: A Review of the Reference Dose and Reference Concentration Processes (available at [HYPERLINK "http://www.epa.gov/raf/publications/pdfs/rfd-final.pdf" \h] [HYPERLINK "http://www.epa.gov/raf/publications/pdfs/rfd-final.pdf" \h]). For example, this document indicates: If there are no appropriate human data, an interspecies UF of 1, 3, or 10 is used. The text should be modified to indicate the range of UFs from 1 to 10.</p> <p>d. This document also indicates the limitation of using UF at the maximum level of 10,000 and does not support the use of UF greater than 3,000 in the decision making process. The text requires revisions to address these topics.</p>	<p>d. The text will be revised to note the upper bound on the total uncertainty factors identified in the 2002 document (noting that TPH is an exception - see response to comment 89).</p>
87	Pages 5-4 to 5-5, Section 5.2	<p>Attached are responses from the Superfund Technical Support Center regarding the surrogate values that should be used to update the RfDs and CFSSs, where appropriate. In addition, the last paragraph of this section can be removed. Findings from the STSC include the following recommendations:</p> <p>a. Overall, weight of evidence analysis identifies 4,4'-DDT as an appropriate surrogate for 4,4'-DDD and 4,4'-DDE based on similarities in structure, metabolism and toxicity profile.</p> <p>b. Altogether, the analysis is unable to suggest any viable surrogates for 2,4'-DDT, 2,4'-DDD and 2,4'-DDE due to limitations in the toxicity database.</p> <p>i. Surrogate analysis for 2,4'-DDT cancer risk values: Considering the lack of conclusive information, comparative analysis of the carcinogenicity and genotoxicity of 2,4'-DDT and structural analogs is not currently possible, preventing the identification of cancer surrogates.</p> <p>ii. Surrogate analysis for 2,4'-DDD cancer risk values: Overall, chronic systemic studies suggest that 2,4'-DDD may be tumorigenic to mice and rats. Weight of evidence analysis</p>	<p>The requested changes to surrogates will be made.</p> <p>The CPG is waiting for guidance from Region 2 and EPA/STSC regarding the relative potency of cis and trans-nonachlor (Comment 87c). Until directed otherwise, the CPG will continue to follow the approach used in the draft BHHRA, which is that the potency of nonachlor and oxychlordane chemicals is comparable to that of chlordane.</p>

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		<p>indicates that 4,4'-DDD could be a potential cancer surrogate for 2,4'-DDD based on structure similarities and overlapping tumor types in mice (lung) and rats (endocrine glands). However, the limited information on the carcinogenicity of 2,4'-DDD in the liver currently available is inadequate to support 4,4'-DDD as a viable cancer surrogate.</p> <p>iii. Surrogate analysis for 2,4'-DDE cancer risk values: Therefore, supporting evidence on the carcinogenicity of 2,4'-DDE is deficient and inadequate to draw any comparisons to the candidate analogs, precluding the identification of appropriate cancer surrogates.</p> <p>c. Paper evaluating the feasibility of cis-chlordane (CASRN: 5103-71-9) as a potential surrogate for noncancer and cancer effects of compounds cis- (CASRN: 5103-73-1) and trans-nonachlor (CASRN: 39765-80-5), and oxychlordane (CASRN: 27304-13-8). Only chlordane was considered for further analysis as a potential surrogate for both noncancer and cancer effects: Overall, chlordane is an appropriate surrogate for both non-cancer and cancer effects of cis- and trans-nonachlor, and oxychlordane chemicals, but the variation in the relative potency of toxicity of these test chemicals from chlordane should be carefully accounted when deriving surrogate risk values and slope factors based on the IRIS document for chlordane (technical; CASRN: 12789-03-6) (U.S.EPA, 1997).</p> <p>d. Paper evaluating the feasibility of naphthalene (CASRN 91-20-3) as a potential surrogate chemical for the oral noncancer and cancer risk assessments of C2-, C3-, and C4-naphthalenes, and, evaluating the feasibility of chrysene (CASRN 218-01-9) as a surrogate chemical for oral noncancer and cancer risk assessment of C2- benzanthracene/chrysene:</p> <p>i. Taken together, naphthalene is not the best surrogate for both oral non-cancer and cancer assessments of C2-, C3-, and C4-naphthalenes as suggested by the requestor. However as described above, 2-methylnaphthalene could be a good surrogate for the non-cancer assessment of C2-, C3-, and C4-naphthalenes. Therefore, fluoranthene is the best possible surrogate (and not chrysene as suggested by the requestor) for the oral non-cancer assessment of C2- benzanthracenes</p> <p>ii. Chrysene is suggested as a possible surrogate for the</p>	

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		cancer assessment of C2-benzanthracenes by the requestor and the STSC agrees with this suggestion.	
88	Page 5-5, Section 5.3	Include a reference to EPA's BMD guidance 2012 available on the EPA Risk Assessment Forum webpage.	The reference will be added.
89	Pages 5-6 to 5-7, Section 5.3	<p>a. Modify the section regarding the uncertainty factor of 10,000 to indicate these values are developed in the Provisional Peer Review Toxicity Values (PPRTVs) as screening levels and are not designed to be used in the decision making process as outlined in the document "A Review of the Reference Dose and Reference Concentration Processes" available at: [HYPERLINK "http://www.epa.gov/raf/publications/pdfs/rfd-final.pdf" \h]</p> <p>b. Change the UFs to a range of 1 to 10 since 10 is not always used as the UF depending on the available data. Values used in IRIS have included 1, 3, 14, and 10.</p> <p>c. Consistent with the recommendations for thallium the text should indicate that the Appendix value will be used for screening purposes only.</p> <p>d. The discussion of the RfD used for TPH C9-C18 should reference the information provided in the PPRTV document which clearly states that this value should be used for screening purposes only and not to support a risk management decision. Information from Indiana should be removed from the paragraph and replaced with the following information from the PPRTV document:</p> <p>"Users of screening toxicity values in an appendix to a PPRTV assessment should understand that there is considerably more uncertainty associated with the derivation of a supplemental screening toxicity value than for a value presented in the body of the assessment." In addition, the text should indicate that despite this evaluation, the concentrations remained below the screening levels. The text needs to be edited to refer the reader to the PPRTV Chemical File.</p>	<p>a. The text describing the combined uncertainty factor of 10,000 for TPH will be revised as requested.</p> <p>b. The discussion of UFs will be revised to indicate that a range of 1 to 10 is available.</p> <p>c. The text will be revised to note that the Appendix RfD for thallium is for screening purposes only. As discussed in the July 29, 2015 call with Region 2, thallium (and TPH) will continue to be retained in the noncancer hazard calculations, and the text will note that HQs are uncertain due to the screening nature of the toxicity values.</p> <p>d. The text here and in the risk characterization will be revised to note that the PPRTV RfD for TPH is for screening purposes only and refer the reader to the PPRTV Chemical File. The Indiana reference will be removed and the quote from the PPRTV document added to the text.</p>
90	Pages 5-7 to 5-10, Section	a. Page 5-8: The last paragraph should state that those chemicals evaluated following the 2005 Cancer Guidelines include the new classification process outlined in the 2005 Cancer Guidelines.	<p>a. The text will be clarified as requested.</p> <p>b. The text will be updated to reference the web-</p>

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	5.4	<p>Other chemicals on IRIS that have not been updated still maintain the old classification system and will be updated as appropriate during the IRIS chemical reassessment. Therefore, both classification systems are provided in the appropriate Tables consistent with the information available at IRIS.</p> <p>b. Page 5-9: The discussion of chemicals with a Mutagenic Mode of Action (MMOA) should clarify whether any other chemicals listed on the Superfund Webpage [HYPERLINK "http://www.epa.gov/oswer/riskassessment/sghandbook/chemicals.htm" \h] [HYPERLINK "http://www.epa.gov/oswer/riskassessment/sghandbook/chemicals.htm" \h] were evaluated. The text should clearly explain whether Chromium +6 was evaluated including an assessment of a MMOA. The text regarding the IRIS review of Chromium should be shortened to indicate EPA is re-evaluating this chemical through the IRIS process.</p> <p>c. Page 5-10: The calculation of ADAFs should be based on the individual years and not the adjusted ADAFs provided at the bottom of the Table on page 5-10.</p>	<p>page listing of the MMOA chemicals, and that none of the other COPCs appear on the list. Page 5-9 of the text clearly states that ADAFs were applied to hexavalent chromium. It should be noted, however, that hexavalent chromium is not listed on the web-page Region 2 has referenced.</p> <p>c. The calculation of the age-weighted ADAFs was done to simplify the risk calculations and is mathematically equivalent to calculating the potential risks for each age range. However, as discussed in the June 15, 2015 call with Region 2, a supplemental set of Table 7s will be included in Appendix H for the COPCs with MMOA.</p>
91	Page 5-10, Section 5.5	Section 5.5 should be retitled as "Dermal Absorption Factor". The text should also identify the specific chemicals where oral absorption factors were applied.	Section 5.5 discusses adjustment of oral toxicity values to account for the absorbed dose calculated for dermal exposures. To avoid confusion with the discussion of dermal absorption fractions in Section 4.3.10.1, the CPG recommends that the term gastrointestinal absorption efficiency, which is consistency with EPA's dermal guidance (RAGS E, Exhibit 4-1), be used. The specific chemicals where gastrointestinal absorption efficiency factors were applied will be identified in the text.
92	Page 5-12, Section 5.6.1	The text here states that the CalEPA (2013) CSF of $1.3E+05$ (mg/kg-day) ⁻¹ for 2,3,7,8-TCDD was selected "in accordance with USEPA's hierarchy (USEPA 2003a)." However, the hierarchy referenced gives equal weight to several other potential sources of toxicity information within "Tier 3." Therefore, citing this hierarchy is not an adequate basis for selecting the CalEPA CSF and additional information will need to be provided consistent with the RSL	The text will be revised to cite EPA's 2013 white paper on selecting Tier 3 values for RSL derivation (USEPA 2013b), which lists CalEPA CSF above HEAST, and was the basis for CPG's use of the CalEPA CSF of $130,000$ (mg/kg-day) ⁻¹ , as well as broad use by other EPA regions and states (see response to comment 154). The use of CalEPA's

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		<p>Questions and Answers #44.</p> <p>As explained previously, the HEAST value of 1.50E+05 should be used to provide consistency with the 1996 Reassessment of Cancer Toxicity for PCBs, including for dioxin-like PCBs and for TCDD TEQ (see Example 3).</p>	<p>dioxin CSF is consistent with EPA's national practice for derivation of risk-based screening levels for use at hazardous waste sites, including Superfund. The selection of the HEAST value is solely at the discretion of the Region.</p> <p>Per response to comment 86b and pursuant to the Region's direction, the HEAST CSF of 150,000 (mg/kg-day)⁻¹ will be used for dioxin-like PCBs and TCDD-TEQ.</p>
93	Pages 5-13 to 5-14	Please see general comments regarding PCB classification for carcinogenicity.	Comment noted.
94	Page 5-14, Section 5.6.2.2	This footnote will need to be revised to indicate there is significant uncertainty based on the limited information regarding the composition of Aroclor 1254 used in the development of the oral Cancer Slope Factor, as discussed in the paper by V. J. Coglianor noted above.	While Coglianor (1998) notes lot-to-lot uncertainty, there is limited uncertainty in the composition of the Aroclor 1254 used in the development of the oral CSF. The compositions of Aroclor 1254 presented in Table 2 of Coglianor (1998) and reported in Table 1 of Mayes et al. (1998) are similar. The CPG disagrees that footnote 37 needs to be revised.
95	Page 5-15, Section 5.6.2.3	Please clarify in the text that the oral RfD for Aroclor 1254 is being used for all PCBs and for all media.	The CPG notes for the benefit of the Region that the text clearly states that the RfD for Aroclor 1254 has been used (see the last sentence of section 5.6.2.3). The phrase "for all PCBs and for all media" will be added to the sentence.
96	Page 5-16, Section 5.6.3	The text should discuss how the oral RfD for naphthalene was selected for alkylated naphthalenes. See comments from Superfund Technical Support Center provided above.	The sentence will be revised to state that based on STSC input, the oral RfD for 2-methylnaphthalene is used.
97	Page 5-16, Section 5.6.4	<p>a. The discussion regarding organic and inorganic arsenic requires further clarification.</p> <p>b. The text should clarify organic arsenic is not being evaluated quantitatively.</p>	<p>a. The text will be reviewed to determine what if any clarification is necessary.</p> <p>b. The CPG notes for the benefit of the Region that the text states on Page 5-17, organic arsenic was evaluated in crab tissue quantitatively. Organic arsenic concentrations were estimated by subtracting</p>

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			inorganic arsenic concentrations from total arsenic concentrations. The HI for organic arsenic was calculated using the MRL for dimethylarsinic acid (DMA).
98	Page 5-17, Section 5.6.5	<p>As discussed under Appendix G, further detail regarding the lead assessment is needed. Information needed includes clarification regarding the model used for the adolescent and the basis, CDC's changes to the recommendations for blood lead levels that are being considered by EPA, and discussions regarding the exposure assumptions used in the lead models.</p> <p>Please note in the uncertainty section that the CDC has reduced their recommended acceptable blood level from 10 ug/dl to 5 ug/dl. EPA is currently evaluating the updated CDC value.</p>	The text will be updated. See responses to comments 194-206.
99	Page 6-1, Footnote 38	Current EPA guidance that updates standard default exposure factors for Superfund (OSWER Directive 9200.1-120, February 2014) recommends continuing use of 70 years as the default "lifetime" duration, pending additional input from EPA's National Center for Environmental Assessment (NCEA). Therefore, this footnote should be deleted.	The CPG does not agree to remove this footnote. Similar to the potential change in the acceptable blood lead concentration that EPA is evaluating (see comments 98 and 195), the footnote provides information regarding a pending change to guidance that is potentially relevant to the risk estimates. It is unclear why it is acceptable for Region 2 to require a reference to one pending change (blood lead action level) and disallow a reference to another (default lifetime duration). The Region needs to be consistent in these instances.
100	Page 6-3, Section 6.2, 4 th Paragraph	<p>The second sentence states "The tables summarizing the HI show both the total HI and HI by target endpoint." However, the tables in Sections 6.3.1 through 6.3.5 only indicate whether an HI is greater than or less than 1.</p> <p>These tables should show the actual total HI and HI by target endpoint. Similarly, these tables should show the actual estimated excess lifetime cancer risks (ELCRs). While tables eventually referenced in Section 6.3.6 do show total HIs and total cancer risks, they still do not summarize "HI by target endpoint."</p> <p>This overall approach was noted in the general comments and</p>	The tables will be revised to include the actual estimates for risk and HI values.

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		should be addressed throughout the report.	
101	Page 6-4, Section 6.3.1, 1 st Paragraph	Remove the last sentence. The evaluation of potential risks from the crab consumption pathway is a reasonable maximum exposure; it is not associated "with a high degree of uncertainty."	The last sentence of the first paragraph in Section 6.3.1 will be removed.
102	Pages 6-4 to 6-24, Section 6.3	<p>Section 6.3, entitled "Risk Characterization Results," includes minimal discussion of the risk characterization results and instead relies on tables which do not transparently present the calculated risk. Receptor-specific subsections should provide and discuss numerical risk estimates for those receptors. Chemicals and exposure pathways contributing the most to risks should be discussed.</p> <p>Receptor-specific subsections should point the reader to the relevant Section 6 summary table(s) for the given receptor, and not just to Appendix I. Tables 6-1 through 6-14 should not simply be mentioned in a single sentence on page 6-22, with no context or discussion. As stated on page 8- 26 of EPA's Risk Assessment Guidance for Superfund (Part A) (1989), "These tables must be accompanied by explanatory text, as described in the previous section, and should not be allowed to stand alone as the entire risk characterization."</p> <p>The risk characterization summary (Section 6.3.6) should provide some discussion of:</p> <ul style="list-style-type: none"> • exposure pathways/media that did not exceed risk thresholds (e.g., even with the conservative exposure assumptions for swimming, estimated risks from surface water contact did not exceed the NCP risk range of 10^{-4} for cancer risk or HI of 1); • context for exposure pathways/media that did exceed risk thresholds (e.g., risks from exposure to sediment were exactly the same for swimmers, waders, and anglers for a given age group because the same exposure assumptions were used for all receptors); and • relative risks among receptors (e.g., that potential risks to anglers may be orders of magnitude higher than risks to other receptors). 	<p>The CPG rejects the Region's characterization that the presentations of risk results in the document are not transparent. The text and tables provide a clear understanding of site risks, with accompanying text that identifies the risk-driving chemicals and exposure pathways.</p> <p>Nonetheless, the text will be revised to provide additional details and context, and the reference to the Section 6 summary tables which is currently on Page 6-22 (Section 6.3.6) will be included with the discussion of each receptor.</p>

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103	Page 6-9, Section 6.3.1.4, Table	Footnote (a) is confusing as written. Please revise to "Cancer risks represent exposures for a child and adult over a 30 year period, while non-cancer hazards provided in the previous subsections are calculated for specific age ranges and not combined." This also applies to other tables in Section 6.3.	The footnote will be revised as follows: "Potential cancer risks in this table represent exposures for a child and adult over a 26 year period, while potential cancer risks and non-cancer hazards provided in the previous subsections are calculated for the specific age ranges listed on the table and not combined."
104	Page 6-11, Section 6.3.2.2, Table	The potential risk under RME scenario for RM6-9 should be "within the NCP risk range" based on RAGS D Table 9.33.	The potential risk will be updated based on the results of the updated risk calculations.
105	Page 6-12, Section 6.3.2.2, Table	The total RME cumulative risk should be =10-4**. In the footnote, please add the following footnote for **: "Cumulative risks for RM 6-9 and RM 6-9 east bank only. The cumulative risks for the remaining RMs and site wide are within the NCP risk range for the adolescent swimmer."	The potential risk will be updated based on the results of the updated risk calculations.
106	Page 6-18, Section 6.3.3.4, Table	In the footnote, please revise the text to "...The cumulative risks for the remaining RM and for site wide are within the NCP risk range."	The footnote will be revised.
107	Pages 6-23 to 6-24, Table	This table should include the total cumulative risks for RME and CTE scenarios.	The total cumulative risks and hazards for RME and CTE scenarios are currently presented in two separate tables (page 6-23 for RME and 6-24 for CTE). If space permits, the two sets of results will be combined in one table.
108	Pages 6-25 to 6-27, Section 6.4	Section 6.4, entitled "COC Identification," limits discussion of specific COCs to a couple of examples with pesticides and PAHs in one paragraph (bottom of page 6-26). The text does not discuss dioxins/furans or PCBs – chemicals contributing the most to risk estimates for this site, nor the relative contribution to risk of all the COCs identified. This section will need to be rewritten to discuss the chemicals that are driving the risks at the site and to discuss the relative	The text will be revised to discuss the chemicals driving site risks and the relative contributions. As requested by Region 2 in the June 19, 2015 letter, the term "COCs" will be replaced with "potential COCs" (see response to comment 8).

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		contribution of COCs to total risk estimates.	
109	Page 6-26. Paragraph 1.	This page has a discussion regarding the further refinement of COCs in the FS based on a number of risk assessment considerations i.e., background, robustness of the chemical toxicity assumptions, estimates of exposure point concentrations, the reliability of the exposure assumptions, and issues associated with sampling and analysis and the CTE analysis. The risk assessment is the appropriate venue for this discussion and re-evaluation of the risk assessment in the FS is not appropriate. Further, the CTE provides an additional source of information but the decision is based on the RME assessment. This further evaluation is not necessary.	The text regarding further refinement of COCs in the FS will be removed.
110	Page 6-28, Section 6.5 1 st Paragraph, 2 nd Sentence	The EPA guidance cited here (USEPA 2002c) does not actually call for calculating background risks. Rather, the guidance recommends a comparison of site and background concentrations, and a discussion of how elevated background concentrations contribute to site risks. However, RAGS Part A (USEPA 1989) (p. 5-18) does state that "if background risk might be a concern, it should be calculated separately from site-related risk," and could be cited here to support presentation of background risk estimates.	Appendix B of EPA's background guidance (2002c) states that "the Risk Characterization should include a discussion of elevated background concentrations of COPCs and their contribution to site risks." This was accomplished in the BHHRA by calculating background risks in a manner consistent with the calculation of site risks, such that the contribution of COPCs in background to site risks can be characterized. The CPG maintains that this approach is consistent with EPA's guidance on background. The reference to RAGS Part A (USEPA 1989b) will be added.
111	Page 6-28, Section 6.5.1	This section will need to be updated in the revised draft of the document. In general, more explanation about the choice of background locations should be included in this section. In addition, Appendix L requires a more in-depth discussion of the logic process used in making these decisions (see comments on Appendix L for more detail).	As described in Appendix B of the RARC, Region 2 selected three areas to represent background conditions for the LPRSA: 1) Upper Passaic River (UPR); 2) Jamaica Bay; and 3) Mullica River. The selection of background locations in the UPR is provided in the approved Reference and Background QAPP (Windward 2012).
112	Pages 6-28 to 6-35, Section 6.5.2	Background risks must be calculated in a manner consistent with risk assessment guidance, using the 95 percent UCL on the arithmetic mean and not a simple arithmetic mean. Specifically:	The background risk evaluation will be revised to present risks based only on the lower of the UCL and maximum, and will be labeled as the RME scenario.

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		<p>Sections 6.5.2 misrepresents the UCL concentrations used in the risk calculations as “upper-bound” values. The concentration values used (i.e., 95 percent upper confidence limit of the arithmetic mean) are estimates of the arithmetic average concentration of each contaminant at the site accounting for uncertainties in the data, as accurately described in Section 4.</p> <p>From EPA's Supplemental Guidance to RAGS: Calculating the Concentration Term (1992), “Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent upper confidence limit (UCL) of the arithmetic mean should be used for this variable. The 95 percent UCL provides reasonable confidence that the true site average will not be underestimated.”</p> <p>A simple arithmetic mean from the site data does not account for uncertainties in that data. Such uncertainties can be pronounced if the number of samples is limited and/or there is a lot of variability in the data. If you took multiple sets of the same number of samples from the site, the arithmetic mean would differ each time. The 95 percent UCL is a more robust statistic for estimating the true mean.</p> <p>Discussions of the UCL concentration statistic in Section 6.5.2 and Appendix L should be corrected, the “mean” scenario should be removed, and the “upper-bound” scenario should be correctly labeled as the RME scenario.</p> <p>Tables in these sections will need to be updated as well.</p>	
113	Pages 6-28 to 6-35, Section 6.5.2	This section should be revised as per General Comment 13.	See response to comment 13.
114	Page 6-35, Section 6.5.3	This section should be removed. It is not appropriate for an EPA human health risk assessment.	The CPG does not agree to remove the discussion of other sources of risk as it provides useful context for understanding overall risks to human health.
115	Chapter 7, General	The uncertainty section is very long and inclusive of potentially valid but secondary information on the shortcomings of risk assessment methodology. A meaningful uncertainty section should be a balanced appraisal of major uncertainties that will significantly affect the site specific numerical risks. The entire chapter needs to be	<p>The CPG rejects and disagrees with the broad and unsubstantiated claims made by the Region concerning the uncertainty section. See response to comments 1 and 12.</p> <p>While Workgroup review, technical/peer reviews, and</p>

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		<p>refined to focus on those key uncertainties that could affect the calculated risk.</p> <p>As noted in the general comments, statements contesting standard risk assessment methodologies, procedures and values should not be included here. Further, the chapter should address both over and underestimates of risk; not all uncertainties lead to an overestimate of risk. It is also not appropriate to indicate how the uncertainty information will be used in the risk management process. The goal of the risk assessment is to support the risk management decision, but not to make the decision.</p> <p>The section states several times that risk would be less if "more realistic" assumptions were used. This language is unsupported. The uncertainty section can look at the effects of using different assumptions, but these are not necessarily more realistic. Please remove this language from the document.</p> <p>Some specific concerns are highlighted below.</p>	<p>the comment process are powerful tools in reaching broad and credible consensus about the current state of the science, it would seem common sense and technically sound to acknowledge the ongoing development of knowledge in the risk assessment process. The process is not meant to be hobbled by out-of-date science for the decade or more that the guidance review/update cycle can take. Surely it is within the discretion of the RPM or other risk manager to weigh new science and shifting weights of evidence in the process of risk management decision making.</p>
116	Page 7-1, Introduction, 2 nd Paragraph	Consistent with the general comment on this chapter, please delete the 3 rd and 5 th sentences from this paragraph, and revise the remaining language, as appropriate.	The fifth sentence will be removed from the second paragraph of the introduction to the Uncertainty Evaluation. The third sentence simply notes the existence of alternative plausible assumptions for some parameters, which is appropriate for a discussion of uncertainty.
117	Pages 7-1 to 7-3, Section 7.1.1	<p>Consistent with RAGS Part D, a summary of the data evaluation and its utility in the risk assessment should be developed. The planning worksheets on data usability are available at: [HYPERLINK "http://www.epa.gov/swerrims/riskassessment/ragsd/planning.htm" \h].</p> <p>The section does not give an overall completeness summary for tissue data. A summary statement of usable results for tissue samples, similar to that for surface water and sediment, should be added to this section.</p>	See response to comment 48.
118	Pages 7-3 to 7-6, Section 7.1.2	The discussion of chemical selection should also indicate the potential underestimates of risks for chemicals lacking toxicity information.	The text will be revised to note the potential underestimation of risks for chemicals lacking toxicity data.

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		This section should contain some discussion of the COPC selection process for fish tissue. Following our direction to group COPCs across species, this would be a good place to discuss the uncertainties associated with any COPCs that might differ between species.	The text will be revised to note the uncertainties associated with differing COPCs among species.
119	Pages 7-4 to 7-5, Section 7.1.2.1, Summary	The text should state that the chemicals not detected with detection limits above RSLs can result in an underestimate of risk/hazards. More discussion of this issue in the text.	<p>The text will be revised to note that chemicals not detected with detection limits above RSLs can underestimate risk. The text will also note that for some chemicals, the RSLs are also below method detection limits (MDLs), and the difference between MDLs and reporting limits will be explained.</p> <p>The CPG notes for the benefit of the Region that the text already includes a thorough analysis of this issue by medium, with supporting tables and text, and concluded that chemicals not detected with detection limits above RSLs would likely contribute negligibly to total estimates of risk/hazard. Besides including an upfront statement to the effect that not including chemicals not detected with detection limits above RSLs can underestimate risk/hazard, the CPG believes this issue has been sufficiently addressed in the text.</p>
120	Page 7-6, Section 7.1.2.2	The first full sentence at top of the page should give the reference and explain the basis for stating that the New Jersey criterion for cyanide "may be a more relevant metric." This is of importance since it is not clear that this determination is based on risk.	The text will be revised to include the New Jersey water quality reference, and the basis for the statement regarding the relevant metric.
121	Page 7-6, Section 7.1.3	This section should be removed from the uncertainty section. A detailed discussion of background was included in the Risk Characterization chapter, consistent with guidance.	This section will be removed from the text.
122	Pages 7-6 to 7-7; Section 7.2.1	The language describing the RME individual should be revised to include a description of the RME individual and how it is evaluated. As described in the Standard Default Exposure Assumption guidance, the goal of RME is to combine upper-bound and mid-range exposure factors in the exposure equation so that the result represents an exposure scenario that is both protective and	The text will be revised to further describe the RME individual and how it is evaluated under Superfund.

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		<p>reasonable, not the worst possible case since it includes a mix of high end and average exposures. The current text suggests this is a “worst case” scenario and requires revision.</p> <p>The discussion at the top of page 7-7 requires further clarification based on the combination of average and high end exposure assumptions that are used in the evaluation of the RME individual. The text also needs to clarify that the decision is based on the RME individual and not the CTE individual.</p> <p>The text should also state that many of the values are standard default exposure factors that are used at Superfund sites across the country.</p>	
123	Pages 7-7, Section 7.2.1	<p>A sentence should be added to the last paragraph of this section stating that the exposure factors were updated to reflect the Superfund Standard Default Exposure Factors published in 2014. As was noted previously, the entire risk assessment should be updated using the new EPA guidance values, except for exposure duration.</p>	The text will be revised to note that the BHHRA has been updated to reflect the latest exposure factors.
124	Page 7-8, Section 7.2.1.2, Introduction	<p>Along with those factors mentioned in 3rd sentence of this paragraph, the text should also state urban populations often have less opportunity to travel to more desirable locations for recreation.</p> <p>This change should also be addressed on Page 7-10, Section 7.2.1.3.</p>	The text will be revised to include ability to travel as a factor affecting site visitation decisions.
125	Page 7-8, Section 7.2.1.2, Sediment Ingestion Rates	<p>The text should acknowledge that these issues were considered in the externally peer-reviewed updated 2011 Exposure Factors Handbook, but this update still recommends use of the same values that were recommended previously.</p> <p>In the last sentence of this section, the word “likely” should be changed to “may.” The text does not address the characteristics of sediment that may result in material spending more time on the skin and being more available for ingestion.</p> <p>The units in this section should be mg/day and not g/day.</p>	<p>The text will be revised to note that the issues were considered in the 2011 EFH, which is cited in the first sentence under Sediment Ingestion Rate.</p> <p>The last sentence will be revised as requested.</p> <p>The units will be corrected to mg/day.</p>
126	Page 7-9,	<p>While the urban setting is a given, the other reasons listed here for limited swimming may be present currently, but could change in the</p>	The text will be revised as requested, including that estimated risks posed by swimming did not exceed

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	Section 7.2.1.2, Surface Water Exposure Assumptions	<p>foreseeable future as towns along the river improve their waterfronts. The conclusion here may be appropriate for current exposures but not for future exposures. Suggest ending the paragraph with:</p> <p>“...lead to overestimates of current exposure to LPRSA sediment and surface water via swimming. They do, however, provide a conservative estimate of risk from swimming exposures for areas with fewer visible deterrents and more access points.”</p> <p>It should be noted that even with the conservative exposure assumptions for swimming, estimated risks from surface water contact did not exceed risk targets. It should also be noted that risks to swimmers from exposure to sediment equal those to waders (the same exposure assumptions were used for both receptors).</p>	the NCP risk range and that hazards did not exceed the goal of protection of an HI=1 even using conservative exposure assumptions.
127	Section 7.2.1.3, Pages 7-10 to 7-13, Fish and Crab Consumption Exposures	<p>a. EPA provided details regarding the selection of the fish consumption surveys for the Lower Passaic River. The text needs to clarify that the Burger survey was for the Newark Bay Complex and not Newark Bay alone. The text also needs to acknowledge that EPA has determined it cannot rely on the results and conclusions of the TSI creel-angler survey, as noted in letters to the editor submitted by EPA and NJDEP.</p> <p>b. The text needs to provide a more even presentation of information, consistent with the results of the Dispute Resolution. Key points to emphasize include: the Ingestion Rates (IRs) developed for use for the LPRSA are comparable to those developed for other sites within Region 2; the Burger and Connolly studies were reviewed through institutional review boards, which is not the case with the other surveys mentioned; and based on the differences in populations the risks may be underestimated.</p> <p>c. The text provides information on the CPG survey, which was not overseen by EPA. Lacking complete information (e.g., metadata), EPA has not been able to evaluate or understand the method by which the CPG converted the results of the CAS to a fish consumption rate. Therefore, reliance on the results of this survey is premature.</p> <p>d. The text regarding the U. S. Department of Agriculture (USDA) Continuing Survey of Food Intakes by Individuals is not an appropriate comparison since it represents a national market-</p>	<p>a. The text will clarify that the Burger survey was for the Newark Bay Complex, with the note that it did not include locations on the LPR. The BHHRA document (Section 4.3.6.1) already states the Region 2 has determined it cannot use the TSI site-specific survey.</p> <p>b. A table comparing the LPRSA fish ingestion rates to recreational angler rates used in other Region 2 HHRAs will be added to the text to provide perspective on the LPRSA rates. The IRB review of the surveys selected by Region 2 will be noted. The text already notes that the impact of differences in populations is uncertain, and it is speculative to state that consumption risks may be underestimated.</p> <p>c. The text will be revised to note that the findings of the CPG's CAS have not been confirmed by Region 2. As previously noted, the results of the CPG's CAS and the basis of the site-specific consumption rate were provided to Region 2 as part of the CPG's comments on the revised FFS.</p> <p>d. The discussion of the rate based on the USDA</p>

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		<p>basket survey.</p> <p>e. On Page 7-13, the text refers to alternate fish ingestion rates. The ingestion rate of 17.5 grams/day was derived for water quality protective criteria to protect the general public, including both consumers and non-consumers. For purposes of this risk assessment we are focused on exposures to consumers only and therefore this is not a valid comparison. The fish ingestion rate of 7.5 mentioned in relation to the Lower Duwamish Waterway is based on the consumption of pelagic fish. The study includes a number of other ingestion rates for species where the total fish ingestion rate is higher, including an IR of 97.5 gram/day for members of the Tualip Tribe.</p> <p>Discussion of both these ingestion rates should be removed from the document since they do not represent an RME individual.</p>	<p>CSFII will be removed.</p> <p>e. The 17.5 g/day rate used in setting water quality criteria was updated by EPA to 22 g/day in 2014 based on more recent NHANES data, Calculation of the rate assumes that all respondents are consumers of fish/shellfish, at least occasionally (USEPA 2014). The rate represents the upper-bound (90th percentile) on consumption of all sources (including self-caught, storebought, restaurant, gift) of freshwater and estuarine fish and shellfish by the general population. It serves as a conservative point of comparison for the LPRSA RME angler in that it includes both fresh and estuarine fish and shellfish from all sources. The 17.5 g/day rate was included in Region 2's 2012 Fish Ingestion Tech Memo as one of several available consumption rates. The CPG maintains the rate is a relevant point of comparison for an uncertainty evaluation. The 7.5 g/day rate was presented in the LDW BHHRA to provide the public with information on risk associated with consuming one-meal-per-month. The 7.5 g/day also coincides with the rate of benthic fish consumption reported for the Tulalip tribe; a rate of 8.1 g/day for pelagic fish was reported, for a total of 15.6 g/day of fish for the Tulalip tribal adult angler (Windward 2007). The remainder of the 97.5 g/day total seafood consumption rate identified in Region 2's comment consists of shellfish (crab, clams and mussels). Again, the CPG maintains that presentation of the alternative one-meal-per-month rate in the uncertainty evaluation of the BHHRA is appropriate and provides useful information to the public and risk managers.</p>
128	Section 7.2.1.3, Page	There is a typo in the footnotes; there are two "b"s and no "c".	The second "b" will be revised to "c".

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129	Page 7-14, Section 7.2.1.3, Fraction Ingested for Fish	<p>a. The title for this section should be changed to “Fraction from Source for Fish Ingestion”.</p> <p>b. Please add the following text after the first sentence: “Given the 17- mile extent of the LPRSA and the variety of fish species it can support, a sizeable recreational angler population is considered likely to catch a substantial fraction of their fish from the LPRSA. In addition, it is expected that a portion of the population do not have the means to easily travel far from the LPRSA. However....”</p> <p>c. The third sentence in this section should start “The consumers of LPRSA fish who do travel out of the area....”</p> <p>d. Please change the final sentence to read “...likely overestimates risk from fish consumption for those of the LPRSA anglers who catch and consume fish from outside the LPRSA.”</p>	<p>a. For consistency with the definition presented in Section 4.3.6.2, CPG suggests revising the title to “Fraction Ingested from Contaminated Source”, which is consistent with RAGS Part A (USEPA, 1989b).</p> <p>b. The CPG disagrees that the size of the LPRSA or variety of fish species available are appropriate or sufficient factors for suggesting that “a sizeable recreational angler population is considered likely to catch a substantial fraction of their fish from the LPRSA.” This statement by the Region is highly speculative, lacks any documented foundation, and is not supported by the CPG’s CAS. Further, based on the CPG’s fish community surveys, the relative abundance of some species, including largemouth and smallmouth bass and northern pike, is likely insufficient to sustain multiple anglers consuming these species at RME rates. The following text after the first sentence will be added: “Given the 17-mile extent of the LPRSA, the fishery it supports, and the proximity of anglers who may not have the means to travel far, it is possible that some anglers catch a substantial fraction of their fish from the LPRSA. However,”</p> <p>c. The third sentence will be revised as requested.</p> <p>d. The final sentence will be revised as requested.</p>
130	Page 7-14, Section 7.2.1.3, Fraction Ingested for	The title for this section should be changed to “Fraction from Source for Crab Ingestion.” Please remove the text and table starting with “An example of the effect of changing FI...” The new final sentence should read “Based on the available information, it is likely that the assumption that 100% of the crab consumed comes from the	For consistency with Section 4.3.6.2, CPG suggests revising the title to “Fraction Ingested from Contaminated Source”, which is consistent with RAGS Part A (USEPA, 1989b).

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	Crab	LPRSA may overestimate risk for anglers who catch and consume crabs from outside the LPRSA."	As discussed in the June 24, 2015 call with Region 2, the text will be clear that the evaluation of alternative FI values is an example to illustrate the impact on risk. The term "more realistic" will be replaced with "alternative". In response to the additional concern regarding comment 130 raised in Region 2's July 15 letter, the table clearly states in the header column that the fraction of crab diet relates to the LPRSA, not crab from outside of the Study Area.
131	Page 7-15, Section 7.2.1.3 Cooking Loss	The first paragraph of this section on this page states that it is "unrealistic" to assume that there is never any cooking loss. The language should be revised to state that it is "very conservative" to make this assumption. Further, the second to last sentence of this paragraph "more average values" are used in the CTE scenario, not more realistic.	The text will be revised as requested. The term more realistic will be struck.
132	Page 7-17, Section 7.2.1.3, Cooking Loss	Second sentence of the first full paragraph on this page: add the phrase "for the CTE scenario" to the end of this sentence.	The text will be revised as requested.
133	Page 7-17, 7.2.1.3, Angler Body Weight and Exposure Duration	This section should be removed.	This section will be removed as the updated EPA default adult body weight of 80 kg will be used in the risk calculations.
134	Pages 7-17 to 7-18, Section 7.2.1.4	The introductory text requires editing to highlight the most important points regarding the fish/crab consumption. The current text includes a lot of speculation regarding the amounts of fish consumed, non-resident fish species and consumption of both fish and crabs. It is recommended that the text highlight the most important aspects of the analysis i.e., risks are above the risk range; even considering consumption of individual fish species the analysis results in cancer risks exceeding the NCP risk range and non-cancer health hazards that exceed the goal of protection of an HQ = 1.	The CPG disagrees that the text includes speculation about types or amounts of fish consumed. Per response to comment 4, the text will be revised to present the mixed diet without carp. The text will also be revised to note that regardless of the mixed diet, the risk targets will be exceeded for the RME scenario and CTE non-cancer, and within the NCP risk range for CTE cancer.

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		While discussing the uncertainty of estimating a mixed fish diet, the point should also be made that whatever mixed diet of LPRSA fish is consumed, the NCP risk range and the non-cancer health hazard goal of protection will be exceeded for the RME scenario. For the CTE scenario, cancer risks will be within or exceed the NCP risk range and the goal of protection for non- cancer health hazards will be exceeded for any mixed fish diet.	
135	Page 7-18, Section 7.2.1.4	Footnote 46 should either be removed or revised, as per Comment 42.	Footnote 46 will be removed.
136	Page 7-18, Section 7.2.1.4, Fish Tissue Type Consumed	The last sentence of this section should be revised to state that fish consumption risks “may be several times higher than the fillet-based risks....” Even if the risk is doubled, that is significant.	The text will be revised as requested.
137	Page 7-19. Section 7.2.1.5. Consumption of Other Biota	Please remove the second paragraph of this section. Instead, state that there is anecdotal evidence that turtles are being occasionally caught and potentially consumed, but it is unlikely that site risks have been underestimated by not quantitatively evaluating consumption of LPRSA biota other than fish and crab since the frequency of consumption of turtles is likely less than for fish and crab.	The second paragraph of Section 7.2.1.5 will be revised as requested.
138	Page 7-19. Section 7.2.2. Estimate of Exposure Point Concentration s	The last three sentences of the paragraph from Pages 7-19 to 7-20 should be deleted. The statements are inaccurate and contradict language included earlier in the same paragraph. Note that we agree that the dataset is robust, but that does not mean that a simple arithmetic average should be used in place of the 95% UCL identified in EPA's guidance.	<p>This text gets, in part, to the fact that Region 2 directed the CPG to analyze many of the largest fish for tissue chemistry, resulting in a tissue dataset that is biased high relative to the LPRSA fish population as a whole or the catch and keep habits of LPRSA anglers. The use of a 95% UCL on large fish further leads to a very conservative EPC for estimating long-term exposure.</p> <p>The last three sentences of the paragraph will be revised as follows:</p> <p>“As previously discussed in Section 7.1, the data sets used in the BHHRA are robust and generally biased high, such that it is unlikely that the use of the 95%</p>

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			UCL (or maximum) underestimates actual exposure concentrations.”
139	Page 7-20, Section 7.2.2	<p>A sensitivity analysis was performed to compare UCLs calculated using both ProUCL versions for several COPCs and media. While differences were often minimal, there was one instance (benzo[a]pyrene in blue crab) where the UCL calculated using Version 5.0.00 was 80% greater than the UCL calculated using Version 4.1.01. In light of this example, the conclusion that “the use of Version 4.1.01 UCLs in this BHHRA does not significantly over or underestimate potential risks” is not adequately supported. What feature of the benzo(a)pyrene data set caused the UCLs to differ so significantly? What other data sets evaluated using Version 4.1.01 have that feature and may have therefore been underestimated by up to 80%?</p> <p>The text should also describe how the non-detects were addressed in the calculations and the potential uncertainty in this approach.</p>	<p>The CPG disagrees that one instance of significant difference out of the 21 instances with little to no difference is sufficient basis to undermine the conclusion that the use of Version 4.1.01 of ProUCL does not significantly over or underestimate potential risks. It is unclear what feature of the dataset caused the UCLs to differ, however, it may be related to frequency of detection (~40%) and the range of detects and detection limits. The BaP crab tissue dataset and ProUCL outputs will be evaluated; if a feature is identified, other tissue datasets with this feature will be evaluated to determine whether the UCLs may be underestimated. Results will be summarized in this section of the uncertainty evaluation.</p> <p>The text will be revised to include a discussion of how non-detects are handled by ProUCL and potential uncertainty.</p> <p>Last, as agreed in the June 15, 2015 call with Region 2, version 5.0 of ProUCL will be used to calculate any new UCLs.</p>
140	Page 7-20 to 7-22, Section 7.2.2.1 Uncertainty in Surface Water EPCs.	The language in this section will need to be updated to reflect inclusion of all of the previously unvalidated surface water data in the next version of the document. When doing so, please keep in mind that it is important to place the information about uncertainty in context. Specifically, the site-wide cancer risks and hazards due to exposures to surface water were within the NCP risk range and below the goal of protection of an HI = 1. .	The text will be revised accordingly, including reference to surface water direct contact risks that are within or below EPA's risk targets.
141	Page 7-22. Section 7.2.2.2, Uncertainty in Sediment	The evaluation needs to be expanded to include the additional data collected in 2013. This section will need to further expand the discussion regarding the overall impacts of this evaluation on the calculated cancer risks and non-cancer health hazards.	The text will be revised accordingly, including reference to sediment direct contact risks that are within or below EPA's risk targets.

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	EPCs.		
142	Page 7-25, Section 7.2.2.5, Assumption of No Degradation	It is not appropriate to discuss this topic in the BHHRA. The concerns raised here will be addressed in much greater detail elsewhere as part of the RI/FS process. Please remove this section.	<p>The CPG disagrees that it is inappropriate to note in a baseline risk assessment, and specifically, a discussion on uncertainty in exposure point concentrations, that environmental degradation has not been factored into the exposure concentrations used to calculate long-term risk/hazard. Section 6.5 of RAGS Part A identifies a number of factors that affect exposure concentrations, including fate processes such as biodegradation and photolysis (USEPA 1989b). It is appropriate to note the conservative assumption of no change in concentration over many years of exposure.</p> <p>The CPG does not agree to remove this section. However, CPG will replace the last sentence of the section with a statement that refers to the reader to the RI for more information.</p>
143	Pages 7-27 to 7-28, Section 7.2.3.1	<p>For TCDD-TEQ, this section notes that the dermal absorption fraction (DAF) decreases when the fraction organic carbon (foc) content of the sediment increases. We continue to support use of a DAF 0.03 for TCDD-TEQ, for the following reasons:</p> <ol style="list-style-type: none"> The average foc of sediment contacted over time (either the arithmetic mean or, better yet, the 95% UCL of the arithmetic mean) should be used to determine the appropriate DAF. This section notes that the average foc is 4.6%, which would support use of a DAF of 0.03 for TCDD-TEQ. The samples listed in this section do not appear to be on Figure 3-1 of the report that shows accessible sediment sample locations. These foc data were in fact collected from deeper parts of the river, and areas outside the "accessible sediment" zone evaluated in the BHHRA. As such they are not relevant to exposures estimated in this report. The average foc should be calculated from data collected within the exposure area. 	<ol style="list-style-type: none"> Agreed. This is what the section says. These samples simply provide bounds on foc within the sediment overall. However, the text will be revised to list foc for samples of accessible sediment.
144	Page 7-28,	EPA evaluated the Mayes study as part of the Housatonic Risk Assessment. The following summarizes EPA's concerns regarding	The text will be revised to note EPA's concerns regarding the Mayes study. It will also be noted that

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	Section 7.2.3.1	<p>this study:</p> <p>EPA's Superfund Dermal Workgroup (EPA, 2001) reviewed the data submitted by Mayes in the HHRA and concludes that two protocol design features preclude the use of this study as the basis for a dermal absorption factor to be used in the Housatonic HHRA (Vol. I, p. 2-21; Vol. IIIA, p. 4-26). The first feature was that the monkeys were not restrained during the exposure period, as they were in the Wester et al. (1993) study, prompting concern that the lack of restraint could result in loss of soil contact with the skin at the test area and thus lead to a lower than expected applied dose. The second feature was that the study did not control for "monolayer" conditions. This concern is based on the theory that dermal absorption of PCBs comes only from the soil monolayer in immediate direct contact with the skin, and that by using a smaller particle size and the same application rate used by Wester et al. (1993), there was a five-fold excess of soil over that monolayer.</p> <p>According to EPA, correction for that "overloading" would result in an estimated dermal absorption rate of 20 percent for the monolayer, which is higher than EPA's 14 percent recommendation.</p> <p>Either remove the text regarding this study from the report or revise the text to incorporate the above information, as appropriate.</p>	<p>humans with dermal exposure (1) also are not restrained throughout their exposure period (which could result in loss of soil contact with the skin) and (2) may be exposed to soil of various particle sizes.</p>
145	Page 7-29, Section 7.2.3.1	<p>It is recommended that the discussion regarding PAHs be removed from this discussion since dermal exposures to PAHs are not a significant risk driver. Moreover, the studies cited in the text were published prior to the issuance of USEPA 2004b (RAGS Part E) and, therefore, were presumably reviewed and considered in the preparation of this peer reviewed guidance.</p>	<p>The CPG agrees that dermal exposures to PAHs are not a significant risk driver at the LPRSA (direct contact risks are in the 10⁻⁵ range). The text was included to provide context and completeness (i.e. clarity and transparency) to the reader. Since RAGS Part E does not provide a comprehensive list of all publications that were considered throughout the development process (which spans over a decade), it is not appropriate to make assumptions about what was considered during development of the guidance, especially in light of the fact that Magee et al. 1996 incorporates information from two studies that are cited in RAGS E: Yang et al. 1989 and Wester et al.</p>

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			<p>1990.</p> <p>The CPG does not agree that this discussion should be removed. However, the discussion will be revised to reference more recent studies and by removing "by about a factor of 6.5" from the last sentence of the paragraph.</p>
146	Pages 7-29 to 7-31 Section 7.2.3.2	<p>The only chemical with an assigned oral bioavailability value is arsenic. The EPA Technical Review Workgroup for Metals and Asbestos Bioavailability Committee has not approved the use of other bioavailability values for other chemicals. EPA disagrees with providing new bioavailability values that have not been reviewed or adopted by the Workgroup Committee.</p> <p>It is recommended that the text simply indicate the potential for reduced bioavailability that cannot be quantified for the various chemicals identified as COPCs for the LPRSA. The table on Page 7-31 should be removed since these values have not been reviewed or adopted by EPA or submitted to the Bioavailability Committee for review.</p>	<p>The CPG disagrees with the Region's contention that only values that have been reviewed or adopted by EPA or submitted to the Bioavailability Workgroup Committee can be presented in an uncertainty evaluation. While Workgroup review, technical/peer reviews, and the comment process are powerful tools in reaching broad and credible consensus about the current state of the science, it would seem common sense and technically sound to acknowledge the ongoing development of knowledge in the risk assessment process. The process is not meant to be hobbled by out-of-date science for the decade or more that the guidance review/update cycle can take. It is within the discretion of the RPM or other risk manager to weigh new science and shifting weights of evidence in the process of risk management decision making.</p> <p>The text in Section 7.2.3.2 will be revised to remove statements quantifying the potential overestimation by the default assumptions used in the BHHRA; the discussion of specific studies and summary table will be retained.</p>
147	Page 7-31, Section 7.3	In the introduction to this section, the text should provide references to EPA's guidelines and guidance for the development of toxicity values.	The text will be revised as requested.
148	Page 7-31 to 7-32, Section 7.3.1	The text should note that the 2004 RfD/RfC guidance recommends not using values with uncertainty factors greater than 3,000 in the decision making process. The current text describes the use of an appendix value which is not intended for use beyond screening due	The text will be revised as requested.

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		to the levels of uncertainty i.e., Cancer Guidelines and 2004 RfD/RfC guidance..	
149	Pages 7-32 – 7-33, Section 7.3.2.1	<ul style="list-style-type: none"> a. The text should mention EPA's process of public review and comment, external peer-review and response to comments in developing CSFs. b. For dioxin, the text should discuss the use of RSLs and that they are screening values. The value selected for use in this risk assessment is one of a range of values. The text should refer to Section 7.3.6.1, where this issue is discussed in more detail. c. The statements regarding PCBs carcinogenicity data requires further clarification. As described previously, the IRIS files indicate there is suggestive evidence of carcinogenicity and IARC recently classified PCBs as a known human carcinogen. The text should indicate EPA has classified PCBs as a probable human carcinogen based on animal data and suggestive evidence in humans. 	<ul style="list-style-type: none"> a. The text will be revised as requested. b. The text will be revised to that the RSLs are screening values and that the value selected is one of a range of values. The text already refers the reader to Section 7.3.6.1 for more information. c. The discussion of PCB carcinogenicity will be clarified as requested.
150	Page 7-33, Section 7.3.2.2	The last sentence of this section states that few changes have been made to existing CSFs. However, PCBs were updated in 1996 (USEPA 1996) and included a bodyweight to the $\frac{3}{4}$ power extrapolation. This should be noted in the text. Also, in addition to the reference to USEPA 1992d, the 2005 cancer guidelines should be referenced as this approach is described on Page 1-13.	The text will be revised as requested.
151	Pages 7-33 to 7-35, Section 7.3.2.3	<p>The text provides information from a number of other federal agencies and international agencies describing the dioxin toxicity values and their significance. The re-evaluation of dioxin by EPA's Office of Research and Development and the IRIS Program should be mentioned in the text.</p> <p>Here, and throughout the document, there is considerable discussion regarding the on-going dioxin reassessment. The following information should be added to this section to provide a more balanced discussion: highlight EPA's guidance, and the development of CSFs and their uncertainty; acknowledge that EPA has a process for developing CSFs consistent with this guidance, and that further details for individual chemicals are provided in the IRIS chemical files, PPRTVs and other documents supporting the</p>	<p>The CPG notes for the Region's benefit that EPA's ongoing dioxin reassessment is mentioned in the last paragraph of Section 7.3.2.3.</p> <p>The text will be revised to further describe EPA's guidance and process for developing CSFs.</p> <p>The CPG does not agree that the paragraph discussing a potential threshold mechanism of action for dioxin should be removed from the report. Given the importance of dioxin at the LPRSA, it is appropriate to acknowledge relevant scientific debate on the underlying toxicology. As discussed in the June 24, 2015 call, Region 2 will check with EPA's</p>

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		<p>development of toxicity values used in this assessment; and note that the cancer risks may be under- or overestimated depending upon the database of information available for each individual chemical.</p> <p>In addition, the 2nd full paragraph on Page 7-34 should be deleted ("There is also support..."). This information is still under review by EPA and, as the text notes, is not currently recognized by EPA as a potential effect.</p> <p>A BHHRA is not the place to discuss these issues.</p>	ORD on the discussion.
152	Pages 7-35 to 7-38, Section 7.3.3	<p>The bulleted list from Pages 7-35 to 7-36 should be deleted. This information is provided in USEPA 2010d, which is referenced. In fact, much of the information in this section comes directly USEPA 2010d and does not need to be recounted here. Please shorten and revise the section to concentrate on the relative percentage of risk from 2,3,7,8-TCDD, TCDD TEQ and PCB TEQ.</p> <p>As per General Comment 15, information regarding dioxin-like versus non- dioxin like PCBs can be added, including whether enhancement of dioxin-like PCBs was identified.</p>	See response to comment 15.
153	Pages 7-39 to 7-40, Sections 7.3.5 and 7.3.6	<p>EPA has recently finalized several surrogate values. These values are provided in the documentation attached to these comments.</p> <p>As indicated previously, values with uncertainty factors greater than 3,000 should be used for screening purposes only. In addition, appendix values from PPRTVs should only be used for screening as well.</p>	Comment noted.
154	Pages 7-40 to 7-44, Section 7.3.6.1	<p>Please see Comment No. 86 and revise this section accordingly. In addition:</p> <p>It remains unclear why information on state application and use of the values listed in #44 are provided in this risk assessment. The bullets should be deleted. Further, this text presents information on state soil values, while the main decision is based on fish/crab consumption and the discussion of cleanup values is outside the goals of the BHHRA.</p> <p>The text regarding HEAST should acknowledge that the HEAST values were developed specifically for the Superfund Program. The</p>	<p>As discussed in the June 24, 2015 call with Region 2, the bulleted list will be retained, and will be checked to ensure consistency with EPA's RSL FAQ #44.</p> <p>The reference to EPA's summary of state soil cleanup levels for dioxin presented in Table 7-3 will not be removed, as it relates to the range of dioxin CSF used across the U.S. and is consistent with RSL FAQ #44.</p> <p>The text regarding HEAST will be revised to acknowledge the values were developed for the Superfund and RCRA Programs (USEPA 1997b).</p>

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		<p>statement regarding the review by other program offices is not appropriate. Further the text should indicate this value was included in the 1996 Reassessment of PCB Cancer Toxicity.</p> <p>The discussion of EPA's 2010 value should be removed since this document is a draft "Do Not Cite or Quote Value" for external peer review and has not yet been finalized and therefore should not be used in this assessment.</p> <p>The section should note that each of the toxicity values discussed yields risks above the NCP risk range and a non-cancer goal of protection of an HI = 1.</p>	<p>The statement regarding review by other program office is from the Introduction (USEPA 1997b), and as such, is relevant to understanding consensus on toxicity values. The text will be revised to note that the value for dioxin presented in HEAST is included in the 1996 PCB Assessment.</p> <p>The discussion of EPA's 2010 draft value for dioxin will be removed. The text noting that EPA's cancer reassessment is ongoing and referring the reader to EPA's website presenting the <i>Science Plan for Activities Related to Dioxin in the Environment</i> will be retained.</p> <p>The paragraph discussing the basis for the CSF selected will be revised to note that the HEAST value of 150,000 (mg/kg-day)⁻¹ is used at the direction of Region 2. The last paragraph will be revised to note that regardless of the toxicity value used, consumption risks posed by dioxin exceed the NCP risk range.</p>
155	Pages 7-45 to 7-46, Section 7.4.2	<p>The statement that most of the assumptions about exposure and toxicity are upper-bounds or maxima is flawed. The assumptions used in the risk assessment are in fact a mix of average and high-end estimates.</p> <p>First, this section incorrectly represents the chemical concentrations used in this report as 95th percentiles. EPA guidance specifically cautions against confusing these terms. EPA's Supplemental Guidance to RAGS: Calculating the Concentration Term (1992) states, "Although the 95 percent UCL of the mean provides a conservative estimate of the average (or mean) concentration, it should not be confused with a 95th percentile of site concentration data (as shown in Highlight 2)." The figure in Highlight 2 of this guidance that is mentioned clearly illustrates the concept.</p> <p>Second, the section does not acknowledge the several parameters that are from the mid-range of their distributions. In addition to the chemical concentrations, average or median values are used for skin surface area, sediment ingestion rate, adherence factors, body</p>	<p>The text will be revised to clarify that the 95% UCL is not the same as the 95th percentile.</p> <p>The example presented in the text is provided as an example of the quantitative impact of combining multiple high end assumptions.</p> <p>The section will be revised to provide examples of average exposure assumptions used in the risk calculations; however, it will also be noted that the assessment for fish and crab consumption relied on multiple high end assumptions, including consumption rate, fraction ingested of 100%, no cooking loss, and exposure duration.</p>

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		<p>weight, and lifetime. The statistical example presented in the second paragraph assumes use of a soil ingestion rate that exceeds 95 percent of the population. The 95th percentile value of soil ingestion is close to 200 mg/day (EPA's Exposure Factors Handbook, 2011); the RME values for sediment ingestion used in this report ranged from 50 to 100 mg/day for adults and children, respectively.</p> <p>Third, the summary statement at the beginning of the fourth paragraph on page 7-46 is incorrect. The risk assessment approach used here did not employ upper 95% bounds or maxima for most RME assumptions.</p> <p>This section should either be removed or significantly revised to reflect these comments.</p>	
156	Pages 7-46 to 7-48, Section 7.4.3	<p>This introduction to this section mentions toxicological sensitivity (i.e., some people are more sensitive to chemicals than other people), but the substantive discussion focuses on two populations that are or may be exposed under atypical conditions: homeless/transient people and residents. Transients and residents are not as groups more sensitive to chemicals; they would just face potentially higher exposures. This discussion should elaborate on which populations are deemed to be more sensitive to chemicals and explain the basis for that conclusion.</p>	<p>The text in Section 7.4.3 will be revised to elaborate on sensitive populations. The discussion of homeless and residents will be moved to a new Section 7.4.4, Risks to Other Populations.</p>
157	Page 7-47, Section 7.4.3	<p>The discussion of the Homeless/Transients is speculative. At a minimum, the 3rd and 4th sentences of the second paragraph of this section should be deleted ("For example, assuming the transient...").</p> <p>For the residential discussion, the examples provided do not represent a residential exposure period of 350 days/years which would be required to evaluate these risks.</p>	<p>Because of challenges in gaining information on the exposure patterns of homeless/transients, the CPG and EPA agreed to address this receptor group qualitatively, as described in the RARC. The discussion in the text presents a qualitative assessment of potential homeless exposures based on anecdotal and observational data, acknowledging there is uncertainty in the characterization. The text will be revised to remove the third and fourth sentences of the second paragraph.</p> <p>The CPG does not agree that residents contact river sediment and surface water adjacent to their home on a daily basis, due to meteorological limitations as well as the condition of the river itself. The example</p>

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			<p>presented in the text assumes a resident may contact river sediment and surface water up to five times more frequently than the wader receptor (i.e., up to 65 days/year for the child and adult and 200 days/year for the adolescent). The CPG believes this represents a very conservative exposure frequency for residents who may contact sediment and surface water in the LPRSA adjacent to their home.</p> <p>For the discussion of river sediment that may deposit onto backyards following flood events, the text will be revised to discuss what potential risks would be under a residential exposure period of 350 days/year.</p>
158	Page 7-48 to 7-49, Section 7.4.4	This section will need to be updated to reflect other comments provided herein.	The section will be updated in accordance with the CPG's responses to other related comments. The section will be renumbered 7.4.5.
159	Page 7-49, Section 7.5	<p>This section overstates the degree of conservatism in the risk assessment. As noted previously, assumptions regarding media concentrations are representative of the mean, not "statistical upper-bounds." Assumptions regarding exposures are a mix of average values with values that are around the 90th or 95th percentile, not "generally representative of statistical upper-bounds." The result of combining this mix of assumptions is that the final estimate of potential exposure and/or potential risk is conservative, indeed toward the high end of the distribution of potential risks – as intended for the RME. But the estimated risks are not expected to lie above the distribution of potential risks to people who may be exposed to the LPRSA under current and future conditions.</p> <p>EPA recommends that the first two sentences of this section be retained and the rest deleted. Note that the last sentence of this section should be deleted as it is inappropriate here.</p>	<p>The CPG disagrees with the Region's contention that the degree of conservatism in the risk assessment is overstated. The numerous conservative assumptions that were directed by the Region for use in the BHHRA, particularly for the fish and crab consumption pathway, have resulted in an overstatement of potential site risk.</p> <p>The summary paragraph will be revised to be consistent with other revisions in this section, and the last sentence of the paragraph will be removed.</p>
160	Pages 8-1 to 8-7, Section 8.0	This entire section will need to be updated to reflect comments provided herein.	Comment noted.
161	Page 8-1,	The last sentence of the introductory section should be modified as	The text will be revised as requested.

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	Section 8.0	follows: The use of these assumptions results in a conservative (i.e., protective of the RME individual) assessment of human health risks for the LPRSA.	
162	Page 8-2, Section 8.1.1	The discussion regarding background will need to be updated to reflect any changes that are made.	The discussion regarding background will be revised to be consistent with revisions noted in the prior responses to comments.
163	Page 8-2, Section 8.1.2	Please delete the first paragraph of this section. It is not necessary to repeat here.	The first paragraph will not be removed, as it provides important context on the site setting, however, it will be shortened and streamlined.
164	Page 8-3, Section 8.1.2	<p>a. In the second full paragraph on the page, the second sentence should be revised to state, "The scenarios and exposure parameter assumptions are intended to capture exposures under both current and future site conditions."</p> <p>b. Please remove Footnote 54. It is not necessary here.</p>	<p>a. The text will be revised as requested.</p> <p>b. Footnote 54 will be removed.</p>
165	Pages 8-4 to 8-5, Section 8.1.4	<p>In general, this section needs to be updated to reflect changes made earlier in the report. In addition:</p> <p>a. In the fourth sentence of the first paragraph on Page 8-4, the exceedances are principally driven by both TCDD-TEQ and PCBs, with lesser contributions from the other contaminants mentioned. The percentages of the risk contributed by these contaminants should be mentioned. The text will need to be revised to present this information.</p> <p>b. A table presenting the cancer risks and non-cancer health hazards that drive risk should be added to the section, with calculated risk values shown. The table and discussion should present values above the goals of protection of 10^{-6} and an HQ = 1 or an HI = 1 for the same target organ.</p> <p>c. The text regarding background will need to be updated to reflect revisions consistent with earlier sections of the report.</p>	<p>The text will be revised to be consistent with revisions noted in prior responses to comments.</p> <p>a. The sentence will be revised to include the percentages of risk contribution by contaminant.</p> <p>b. A table presenting the risks/hazards driving risk will be added.</p> <p>c. The discussion regarding background will be revised to be consistent with revisions noted in the prior responses to comments.</p>
166	Pages 8-5 to 8-7, Section 8-2	<p>a. Pg. 8-6: Change 170 crabs per year to "approximately 30 meals of 6 crabs per year."</p> <p>b. Pg. 8-7: The second sentence of the last bullet on this page</p>	<p>a. The text will be revised as requested.</p> <p>b. The bullet will be revised as requested.</p>

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		<p>should be deleted.</p> <p>c. All discussion of background should be updated to reflect earlier comments provided herein.</p> <p>d. In the last paragraph of the section, the word “significantly” should be removed from the 4th sentence, and the last sentence should be deleted.</p>	<p>c. The discussion of background will be revised to be consistent with revisions noted in the prior responses to comments.</p> <p>d. The text will be revised as requested.</p>
167	Tables, Figures and Appendices	All tables, figures and appendices will need to be updated to reflect comments provided herein.	Comment noted.
168	Table 3-2	Please add the following acronyms to the footnote: COPC, FSP, LRC, and RI.	The acronyms will be added.
169	Table 3-3	<p>a. Page 1 of 8, to be consistent with Table 3-4, please separate phosphorus from the current “inorganic” group as a separate “phosphorus” group.</p> <p>b. Page 6 of 8, please add the CAS number (91-57-6) for 2-methylnaphthalene.</p>	The requested changes will be made.
170	Table 3-4	Please add COPC acronyms to the footnote.	The acronyms will be added.
171	Table 3-8	<p>a. The qualifiers for minimum and maximum concentrations are showing multiple qualifiers for compounds listed under TPH and most of them are the same qualifier. For example, for tetracosane, n- the qualifier should be “J” instead of “J;J;;J;J”.</p> <p>Only one qualifier should be shown unless there are different qualifiers.</p> <p>b. The text for the location of maximum concentration for endosulfan II and Icosane were cut off. Please revise accordingly.</p> <p>c. Include qualifier “I” in footnote “(a)”</p>	<p>a. This occurs when the minimum or maximum occur in sample/duplicate pair and both the sample and the duplicate have qualifiers. Where the qualifiers are the same, they will be updated to show only one qualifier.</p> <p>b. The table will be revised.</p> <p>c. The qualifier will be added to the footnote.</p>
172	Table 3-9	<p>a. As stated on Page 3-9 (footnote 18), only the high resolution data were used in developing exposure point concentrations. Thus, naphthalene should not be selected as a COPC in</p>	<p>a. Naphthalene will be removed as a COPC in surface water.</p> <p>b. The value has been confirmed and was not</p>

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		<p>surface water since the maximum concentration does not exceed the screening level. Please revise the necessary text and subsequent affected tables.</p> <p>b. Please confirm the maximum concentration for low resolution naphthalene result (8.5 µg/L) since this value seems to be an outlier.</p>	<p>rejected during validation. Based on our review, it does not appear to be a laboratory or other obvious error. Since only the high resolution data are used in the screening and EPC derivation, the result in question will not impact the BHHRA.</p>
173	Table 3-10	<p>Include summary statistics for arsenic, organic in Table 3-10 since the summary statistics for arsenic, organic is presented in Tables 4-25, 4-26, and 4-27.</p>	<p>The summary statistics for organic arsenic, which was calculated as the difference between the total arsenic and the inorganic arsenic concentrations by sample, will be added to Table 3-10 for crab tissue. Note that inorganic arsenic was not detected in the fish tissue samples, and therefore, organic and inorganic arsenic concentrations are not presented for fish.</p>
174	Table 3-11	<p>a. Cadmium, copper, mercury, hexachlorobenzene, and pentachlorophenol are not identified as surface water COPCs; hence, they should be included in this table since it includes all tissue COPCs that are not identified as surface water or sediment COPCs.</p> <p>b. Methyl mercury is not identified as surface water and sediment COPC; hence, it should be included in this table.</p>	<p>a. The listed tissue COPCs will be added to Table 3-11.</p> <p>b. Methyl mercury does not need to be included, as it is represented by mercury.</p>
175	Table 3-12	<p>a. To be consistent, change "xd" to "x(d)" in the benzo(b)fluoranthene under blue crab – hepatopancreas only.</p> <p>b. As per RAGS Part A, Section 5.9.4, iron should be a COPC in surface water and sediment; thus, it should be included in this summary of COPC table.</p> <p>c. Total COPCs for surface sediment should be 32 (not including iron). Please revise accordingly.</p>	<p>a. The revision will be made.</p> <p>b. The RARC plan specifically stated that iron would be considered an essential nutrient, with no mention of comparing to any screening level. Therefore, iron will not be included as a COPC. Per Region 2's July 15 letter, the text will be revised to note that iron exceeded its RSL but is considered an essential nutrient and therefore not included as a COPC.</p> <p>c. The total number of COPCs will be updated pending the update to the sediment dataset</p>

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			to include the SSP2 data. Iron will not be added as a COPC per the Region's July 15 letter.
176	Table 4-1	Inhalation of vapors from sediment and/or surface water is shown as evaluated quantitatively for angler, swimmer, wader, boater, and worker. However, as mentioned on Page 4-4 and Appendix D, inhalation pathway risks are negligible. Therefore, please add to the last sentence in the "Rationale for Selection or Exclusion of Exposure Pathway" stating "however, this pathway is not considered further in the BHHRA because the inhalation pathway risks are negligible" to all receptors.	The requested change will be made.
177	Table 4-3	Delete CF2 which is the conversion from hours to day for all scenarios since CF2 is not used in the intake calculation.	CF2 will be deleted.
178	Table 4-3	The intake equation for all dermal contact to surface water should be revised to dermally absorbed dose.	The intake equation, which was provided on the RAGS Part D tables from Region 2, will be corrected.
179	Table 4-4	On page 1 of 2, the row height for exposure frequency should be increased to show the rest of the rationale.	The row height will be increased.
180	Table 4-6	<ul style="list-style-type: none"> a. A typographic error is noted for dermal-sediment contact value for aluminum. The "(a)" should be "(c)". b. Add footnote "(c)" reference to the dermal-sediment contact value for antimony. c. The dermal-sediment contact values for DDD, DDE, aldrin, dieldrin, and heptachlor epoxide are not listed in RAGS Part E Exhibit 3-4 as noted in footnote "(c)". Instead, these values are listed in the RSL table. Please revise the footnote accordingly. 	<ul style="list-style-type: none"> a. The footnote letter will be corrected. b. The footnote reference will be added. c. The dermal absorption factors for DDD, DDE, aldrin, dieldrin, and heptachlor epoxide are the default values for semivolatile organic compounds from RAGS Part E Exhibit 3-4 (USEPA 2004). As USEPA (2004) is the original source of the value, the CPG believes that RAGS E is the appropriate reference, and will revise the table accordingly.
181	Table 4-7	<ul style="list-style-type: none"> a. Increase the row height for the footnote to show the full formula. b. Include the definitions of "b" and "c" used in equations A-6 through A-8. 	The requested edits will be made.

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182	Table 4-8	<p>Please revise the following, and thoroughly review the entire table:</p> <ol style="list-style-type: none"> UCL for cobalt should be 7.56 and not 8. The frequency of detection for dieldrin should be 140:142 instead of 141:143. The statistics for benzo(a)pyrene could not be reproduced. On page 3-9 footnote, the high resolution data for PAHs were used in developing exposure point concentrations. Based on this, the maximum benzo(a)pyrene concentration will be 19 mg/kg. Please verify and confirm the correct data were used in the calculation. 	<p>Note that values will change based on the inclusion of SSP2 data. Responses below reflect the table prior to the SSP2 update.</p> <ol style="list-style-type: none"> Agreed. The UCL should have been 7.56. The FOD of 141:143 is correct, based on a review of the data in Appendix A as well as the ProUCL output in Appendix F. FOD will be updated to reflect inclusion of SSP2 data. The result for sample LPRH10A based on the low resolution method (SW8270C) is 19 mg/kg. The result from the high resolution method (429M) for that sample is 8.1 mg/kg. The maximum result from the high resolution methods (429M and ID-0016) is 12 mg/kg in sample LPRH16A, as shown in Table 4-8.
183	Table 4-13	<p>Please revise the following, and thoroughly review the entire table:</p> <ol style="list-style-type: none"> The frequency of detection for copper should be 39:39 instead of 34:34. The frequency of detection for dieldrin should be 31:33 instead of 32:24. 	<p>Note that values will change based on the inclusion of SSP2 data. Responses below reflect the table prior to the SSP2 update.</p> <ol style="list-style-type: none"> Agreed. The frequency of detection for copper should be 39:39. The frequency of detection for dieldrin in the table, which reads 32:34, not 24 is correct.
184	Table 4-16	<p>Please revise the following:</p> <ol style="list-style-type: none"> The frequency of detection of naphthalene in Table 4-16 (38:60) does not match the frequency of detection in Table 3-9 (36:60). The maximum concentration of naphthalene in Table 4-16 (0.33 µg/L) does not match the concentration in Table 3-9 (0.069 µg/L). 	<p>Note that values will change based on the inclusion of additional surface water data. Responses below reflect the table prior to the update.</p> <p>Per Comment 172, naphthalene will no longer be identified as a COPC.</p>
185	Tables 4-17 to	The frequency of detection and minimum and maximum	Table 3-10 presents summary statistics for the

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	4-27	concentrations of mercury in Tables 4-17 to 4-27 do not match the values in Table 3-10. Please make the necessary changes.	laboratory reported total mercury and methyl mercury results. The EPCs presented in Tables 4-17 to 4-27 are for the calculated inorganic mercury concentrations (total mercury minus methyl mercury). Summary statistics for inorganic mercury will be added to Table 3-10.
186	Table 4-17	Add subheading "SVOCs" to bis(2-ethylhexyl)phthalate.	The subheading will be added.
187	Table 4-24	Revise the following and make necessary corrections: a. The minimum (0.03 J µg/L) and maximum (0.33 µg/L) concentrations of heptachlor epoxide in Table 4-24 does not match the concentration in Table 3-10 (0.0018 J µg/L and 0.0024 µg/L, respectively). b. The selected EPC values for 4,4'-DDD and heptachlor epoxide should be maximum concentration and not mean concentration.	a. The chromium summary statistics were inadvertently listed under heptachlor epoxide in Table 4-24 (white sucker EPCs). The values of 0.0018 J mg/kg and 0.0024 mg/kg listed in Table 3-10 are correct and will be corrected in Table 4-24. Note that the risk calculations were conducted using the correct value of 0.0024 mg/kg. b. The table will be revised to present the maximum detected concentration for these COPCs (0.016 mg/kg for 4,4-DDD and 0.0024 mg/kg for heptachlor epoxide).
188	Table 5-1	Similar to the Oral Cancer Slope Factor, the Chronic Oral Reference Dose for 2,3,7,8-TCDD should be used for dioxin-like PCBs.	See response to comment 15.
189	Table 6-9	In the footnote, please change "10 ⁻⁶ to 10 ⁻⁴ " to "10 ⁻⁴ to 10 ⁻⁶ "	The requested change will be made.
190	Table 6-12	Please change the following to be consistent with Table 6-2: a. the noncancer hazard to the sitewide CTE adult wader exposed to accessible surface sediment from 0.1 to 0.09 b. the cumulative noncancer hazard to the sitewide CTE adult wader from 0.1 to 0.09 c. the cumulative noncancer hazard to the sitewide CTE teen boater from 0.1 to 0.06	The requested changes will be made.
191	Table 6-14	To revise the cumulative noncancer hazard to the sitewide CTE	The requested change will be made.

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		adolescent and adult angler from "1.0" to "1".	
192	Tables 6-15 to 6-20	To fix the table header and footnote to show the 10 ⁻⁶ , 10 ⁻⁵ , and 10 ⁻⁴ with the proper font superscript.	The editorial change will be made.
193	Figure 4-1	Inhalation of volatiles in outdoor air volatilized from surface water and/or exposed mudflat sediment is shown as complete exposure pathway (marked with solid circle) for angler, swimmer, wader, boater, and worker. However, as mentioned on Page 4-4 and Appendix D, inhalation pathway risks are negligible. Therefore, please add a footnote stating "this pathway is not considered further in the BHHRA because inhalation pathway risks are negligible for all potential receptors."	The footnote will be added.
194	Appendix G, Section 1.0, Page 1	The first paragraph should refer the reader to the section in the main text where lead was identified as a COPC in various media, or repeat the basis for the decision here. A brief explanation for why lead was not a COPC in fish tissue should be added.	The requested edits will be made.
195	Appendix G, Section 1.0, Page 1	<p>The description of the lead assessment in the fourth paragraph needs revisions to indicate that the approach looks at a specific blood lead level and include more information of the lead models for adults and children. For example, the document should indicate: The focus of the integrated exposure uptake biokinetic (IEUBK) model for lead in children is the prediction of blood lead concentrations in young children exposed to lead from several sources and by several routes. The model is a four-step process that mathematically and statistically links environmental lead exposure to blood lead concentrations for a population of children (0-84 months of age). Also, the text should clarify how the adolescent exposures were considered, i.e., which model was used for the adolescent.</p> <p>The text should also describe the goal for lead of 10 ug/dl. It should also mention that the CDC has updated their value to 5 ug/dl and that EPA is currently evaluating the updated value.</p>	<p>It is unclear why in this case, Region 2 is requesting a reference to a value that EPA is currently evaluating, while comment 99 specifically requests that the CPG not reference a value (lifetime) pending review by EPA. As stated previously, Region 2 should exercise consistency in making these comments.</p> <p>For consistency with response to comment 99, a footnote will be added to the text noting the EPA is currently evaluating updating the acceptable blood lead value to the updated CDC value of 5 ug/dl.</p>
196	Appendix G, Section 2.0, Page 2,	Fish should not be included in the second paragraph describing exposure areas to eliminate any confusion about the exposure	The requested changes will be made.

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	Paragraph 2	media evaluated in this appendix. It is recommended that the presentation of the average lead concentration in the evaluated media be expanded to provide the minimum and maximum concentrations identified, to put the average concentrations in context. The average concentration for surface water should also be compared to the drinking water action level of 15 ug/l.	
197	Appendix G, Section 2.1, Page 2, Paragraph 2	The text should not characterize the RME scenario as “worst-case,” nor label the CTE scenario as “more realistic”. The first sentence of the second paragraph should be revised: “In general, the RME scenario is a high-end estimate of potential exposure while the CTE scenario uses exposure factors that are more indicative of the average.”	The requested changes will be made.
198	Appendix G, Section 3.2, Page 3	Discussion of indoor air parameters should be eliminated since exposure to indoor air is not one of the pathways evaluated for the receptor scenarios considered in this lead assessment.	The discussion will be removed.
199	Appendix G, Section 3.3, Page 3	The age range of “6 months to 6 years of age” for dietary lead intake in the second sentence seems to not match the age range presented on the figures on pages 7 and 8 (i.e., 12 months to 84 months). The age range in the text refers to source data for the Food and Drug Administration's (FDA) average ingestion rates of lead in diet, and “6 years” does in fact include the months up to the 7 th birthday. The FDA's default dietary lead intake is 0.0055 mg/day for 6-11 month olds and 0.0058 for 1 year olds as summarized in the IEUBK Guidance Manual (EPA 1994), page 2-31. Both of the values for these age groups round to the 0.006 mg/day mentioned as the lower end of the range in Section 3.3. Thus the data in Section 3.3 and the figures on page 7 and 8 are actually consistent with each other. To avoid confusion, the text in Section 3.3 could be changed from “6 months to 6 years of age” to “from the first birthday to the day before the 7 th birthday”.	The suggested edit will be made.
200	Appendix G, Section 3.3, Page 3	The text in the third sentence should cite EPA 1994a as the basis for the assumed fractional uptake of lead. A reference for the crab ingestion rate of 7 g/day needs to be provided in the final sentence	The references will be added.

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		of this section.	
201	Appendix G, Section 3.4, Page 3, Equation 1	Using the formula in Equation 1 for time-weighted surface water concentrations, the drinking water lead concentrations for child swimmers and waders used in the IEUBK model cannot be confirmed based on the average surface water concentration of 4.9 µg/L and exposure times and exposure frequencies in Table G-2. The text requires clarification to explain the values used.	The drinking water concentrations will be corrected and a table will be included to present the calculations. The revised drinking water concentration for the child swimmer is 0.04 ug/L and for the wader is 0.005 ug/L.
202	Appendix G, Section 4, Page 4, Equation 2	The equations presented in this section are correct; however, <i>Pb_{sed}</i> is not used in Equation 2 and should be removed from the list below Equation 2.	<i>Pb_{sed}</i> will be removed.
203	Appendix G, Section 4.0	The title for this section should include adolescents as well as adults. The text should also state that the adult lead model was applied to adolescents consistent with EPA guidance [HYPERLINK " http://www.epa.gov/superfund/lead/almfaq.htm " \l "input)" \h]/[HYPERLINK " http://www.epa.gov/superfund/lead/almfaq.htm " \l "input)" \h]	The requested edits will be made.
204	Appendix G, Section 6.0, page 8	The discussion of the blood lead models should note uncertainties in applying the adult model to adolescent receptors [HYPERLINK " http://www.epa.gov/superfund/lead/almfaq.htm " \l "input)" \h]/[HYPERLINK " http://www.epa.gov/superfund/lead/almfaq.htm " \l "input)" \h]	The uncertainties will be noted.
205	Appendix G, Section 6.0, Pages 8	The uncertainty section of the text should also indicate the new CDC value of 5 ug/dl that EPA is currently evaluating.	The text will reference the CDC value. However, it is unclear why in this case, Region 2 is requesting a reference to a value that EPA is currently evaluating, while comment 99 specifically requests that the CPG not reference a value (lifetime) pending review by EPA. See response to comment 195.
206	Appendix G, Table G-1	The table indicates a maximum concentration of 2,050 mg/kg in RM 9 to 12. The information should be included in the uncertainty section as a potential outlier. Also, the footnotes in the table should be corrected. The table	The requested discussion will be added and the footnotes will be corrected.

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		includes footnotes a, b, c, and d. However, only footnotes a and b are defined below the table.	
207	Appendix H	<ul style="list-style-type: none"> a. The diet fraction (0.25) was not applied to benzo(a)pyrene in the cancer risk calculation for mixed fish diet. Please revise accordingly. b. The ADAF should be applied to children younger than 16 years, consistent with the cancer guidelines supplemental guidance (EPA 2005). c. The RfD for TCDD should be used for PCB-TEQ non-cancer health hazard calculations. d. For all tables, total non-cancer health hazard excluding total PCBs is stated as "NA". This is incorrect since other COPCs have non-cancer hazard quotient listed. Please revise accordingly. 	<ul style="list-style-type: none"> a. The calculation of risk for the mixed fish diet will be performed as described in response to comment 53. b. See response to comment 90. c. See response to comment 15. d. The tables will be revised accordingly.
208	Appendix I	A footnote should be added to all tables that the table presents risk drivers only (i.e., COPCs with individual carcinogenic risk greater than 10^{-6} and non- carcinogenic hazard quotient greater than 1) and cumulative risks, cumulative hazards, and target organ HIs may be less than shown in Table 7 series (Appendix H) and Table 9 series (Appendix I).	The footnote will be added to the tables.
209	Appendix L, General	Appendix L should be reviewed in full and the approach for deriving background concentrations made consistent with that being finalized for the BERA, as appropriate. The background dataset selected should ultimately be a subset of that used in the BERA. Some of the remaining comments on this Appendix may be superseded by the final approach being developed for the BERA.	The approach used will be consistent with the BERA.
210	Appendix L, General	The text notes that only surface sediment data from within 1.4 miles of Dundee Dam are selected to represent background for this project (Dundee Dam to Interstate 80), even though sediment data further upstream (~ 13 locations for SQT purposes) were also collected. All project-specific surface sediment chemistry data collected from Upper Passaic River locations should be evaluated for incorporation into the background dataset.	As described in the <i>Background and Reference Conditions QAPP</i> (Windward 2012), the 1.4-mile stretch of river between Dundee Dam and Interstate-80 represents a depositional area likely impacted by sources from the upper Passaic River (UPR). Therefore, the sediment chemistry data collected from this area were used to characterize concentrations resulting from upstream sources that serve as inputs

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			to the LPRSA. However, as requested by Region 2, the additional sediment chemistry data collected above I-80 for SQT purposes will be considered for inclusion in the background dataset.
211	Appendix L, Page 1-1, Section 1.0, First Paragraph	<p>a. The 2nd sentence implies that all of the sources listed in the 1st sentence are background sources, but they are not, in accordance with EPA's background guidance. Therefore, the word "background" in front of "sources" in the 2nd sentence should be deleted.</p> <p>b. The 3rd sentence conflicts with the definition of background in EPA guidance that is quoted in the 2nd paragraph of this section and it is not accurate. The sampling that CPG did would capture both anthropogenic and natural background – it was not designed to distinguish between the two, even in a highly urbanized environment. The 3rd sentence should be deleted and replaced with the definition of background in EPA's background guidance (i.e., move the definition from the 2nd paragraph to the 1st paragraph).</p>	<p>a. The text will be revised as requested.</p> <p>b. The text will be revised as requested.</p>
212	Appendix L, Page 2-1, Section 2.1, Second Paragraph, Third sentence	<p>"Although some locations may appear at depths too deep for regular human access, given the potential change in water depths over time, it was conservatively assumed that all locations are potentially accessible." How is this a conservative assumption? Why is this assumption made here when it was not for the LPRSA data?</p> <p>The use of background sediment samples from depths greater than those used in the LPRSA requires justification and may not be appropriate.</p>	<p>The decision to use all samples above the dam was based on the potential for overlying water depths above the dam to change due to changes in flow. Based on USGS gage height data from the past 8 years for RM 17.61 (above Dundee Dam), water levels vary as much as 6 feet with a median of 1 to 2 feet.</p> <p>However, as requested by Region 2, the water depth definition used to identify the UPR accessible sediment data set for background risk calculations will be consistent with the LPRSA (see response to comment 13c).</p>
213	Appendix L, Page 2-3, Section 2.4, Second	"Background values were defined per COC...as the maximum detected concentration in a given data set excluding any outlier concentrations." Guidance regarding the treatment of background data emphasizes comparison of the mean concentration in	As noted in response to comment 13b, a statistical comparison of site and background will be added to provide additional information.

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	paragraph, First sentence	background to the mean concentration in potentially impacted areas (EPA 2002, page 3-1). In addition, for risk assessment purposes, EPCs are derived using the 95% UCL of the arithmetic mean rather than the maximum detected concentration. Additional statistics about background data are provided later in this appendix, so it is not clear why background is defined as the maximum concentration here.	<p>The background risk calculations were performed using the same EPC statistic used for the LPRSA baseline risk calculations (i.e., lower of the maximum detect and 95% UCL), to provide statistically comparable risk estimates. As noted in response to comments 6 and 112, only the UCL statistic will be used in revised background risk calculations; the calculations based on the arithmetic mean will be removed.</p> <p>The maximum concentration after removing outliers is identified as the background value for consideration in defining remediation goals, but is not used in the background risk calculations. This distinction will be clarified in the text.</p>
214	Appendix L, Page 2-3, Section 2.4, Second paragraph, Second sentence	The text states that outliers were identified as the 75 th percentile plus three times the interquartile range of the data distribution based on log- transformed concentrations. However, EPA's Data Quality Assessment guidance (EPA QA/G-9S, Box 2-13, Section 2.3.3) regarding outliers should be followed. The guidance recommends the use of a multiplier of 1.5.	<p>The use of 3 times the interquartile range (3xIQR) is an appropriate screen for outliers. It is consistent with the approach laid out in the RARC Plan, which identified use of an interquartile range and 3x to determine outliers in Appendix B (Windward and AECOM 2013). Region 2 did not provide any comments on this specified outlier approach in their January 2014 comments to the RARC Plan. Further, a threshold of 1.5xIQR unnecessarily removes results reflective of the natural variability associated with background conditions.</p> <p>The CPG also notes that the guidance (section 2.3.3 or Box 2-13 of EPA's 2006 QA/G9) cited by the Region identifies 1.5xIQR as an example for identifying potential outliers. Moreover, EPA's 2009 guidance (EPA 530/R-09-007) states in Section 9.2:</p> <p>"Potential outliers are categorized into two groups:</p> <ul style="list-style-type: none"> • data points between 1.5 and 3 times the IQR above the 75th percentile or between 1.5 and 3 times the IQR below the 25th percentile, and • data points that exceed 3 times the IQR

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			<p>above the 75th percentile or exceed 3 times the IQR below the 25th percentile.”</p> <p>Section 9.2 also includes an example (9-2) that clearly states to:</p> <ul style="list-style-type: none"> • identify potential outliers between 1.5×IQR and 3×IQR beyond the box. • identify potential outliers exceeding 3×IQR beyond the box. <p>It is commonly understood in the statistical literature (Dawson 2011) that 1.5×IQR and 3×IQR provide lower and upper thresholds for potential outliers, with mild or near outliers identified as data points that fall between 1.5x and 3xIQR, and extreme outliers identified as data points in excess of 3xIQR. EPA's 2009 guidance is consistent with the literature regarding the identification of outliers.</p> <p>The example box of EPA QA/G9 which identifies a multiplier of 1.5 as the sole criterion for outlier identification is at best incomplete and possibly incorrect. The use of 3xIQR is both consistent with EPA guidance and statistical literature.</p> <p>As such, the CPG will retain the 3xIQR in its analysis of background data to identify extreme outliers. As an additional analysis, potential near or mild outliers will also be identified using 1.5xIQR to evaluate the sensitivity of the background data sets to this threshold.</p>
215	Appendix L, Page 3-1	The figures in Appendix L provide part of a preliminary data analysis, as called for in EPA's Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites (September 2002, Chapter 4). However, the report should also provide some interpretation of the figures in the text, rather than just present them.	The text will be revised to provide interpretation of the figures presented.
216	Appendix L,	“The majority of background values were identified as the maximum	See response to comment 213.

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	Page 3-1, Section 3.0, First paragraph, Fourth sentence	detected concentration of each data set.” See previous comment regarding this issue on page 2-3.	
217	Appendix L, Page 3-1, Section 3.1, Third sentence	“Mean and upper-bound exposure point concentrations (EPCs) were calculated...” Exposure point concentrations are typically based on the 95% UCL of the arithmetic mean (considered a conservative estimate of the true mean), rather than a simple mean from the data set or an upper-bound value.	Comment noted. Per response to comment 112, background risks will be calculated based on the UCL only.
218	Appendix L, Page 3-2, First sentence	“The EPCs...are presented in Tables L-12 through L-16.” These tables present several summary statistics for the data but do not identify which were used as the EPCs in the risk evaluation. This must be clarified. This comment also pertains to statements about Tables L-20 and L-21 later in the paragraph.	The text will be revised to clarify that the UCL (or maximum if lower) is used.
219	Appendix L, Page 3-2, Final paragraph, and Tables L- 22 through L- 25	The phrase “(mean and upper-bound)” should be removed from the first sentence in this paragraph. Tables L-22 through L-25 should be revised: as noted in earlier comments, the “mean” scenario should be removed, and the “upper-bound” scenario should be correctly labeled as the RME scenario.	The text will be revised as requested, and the mean scenarios will be removed from the background risk calculations.
220	Appendix L, Tables L- 22 through L-25	A footnote (Footnote f) on these tables gives some information about the risk estimates: “All risks calculated using RME assumptions; only EPC differs.” However, there is still no explanation in this appendix about what specific statistics were used for the EPCs. The only statistic that should be used as the EPC is the 95% UCL of the arithmetic mean (or the maximum detected concentration if the 95% UCL exceeds the maximum). As noted above, the “mean” scenario should be removed and the “upper- bound” scenario should be correctly labeled as the RME scenario. Footnote f should be revised to “All risks calculated using RME assumptions”.	The footnote will be revised to clarify that the lower of the 95% UCL and maximum is the basis of the EPC used in the background risk calculations. Footnote (f) will be revised accordingly.

